DOCKET

SUPREME COURT
OF THE UNITED STATES

No. 12-416
Title: Federal Trade Commission, Petitioner
v.
Actavis, Inc., et al.
Docketed: October 4, 2012
Lower Ct: United States Court of Appeals for the Eleventh Circuit
Case Nos.: (10-12729-DD)
Decision Date: April 25, 2012
Rehearing Denied: July 18, 2012
Questions Presented

~~Date~~~	~~~~~~~Proceedings and Orders~~~~~~~~~~~~~~~~~~~~
Oct 4 2012	Petition for a writ of certiorari filed. (Response due November 5, 2012)
Oct 31 2012	Order extending time to file response to petition to and including November 13, 2012, for all respondents.
Nov 5 2012	Brief amici curiae of New York, et al. filed.
Nov 13 2012	Brief of respondent Solvay Pharmaceuticals, Inc. filed.
Nov 13 2012	Brief of respondents Par Pharmaceutical Companies, Inc. and Paddock Holdimgs, Inc in opposition filed.
Nov 13 2012	Brief of respondent Watson Pharmaceuticals, Inc. filed.
Nov 20 2012	DISTRIBUTED for Conference of December 7, 2012.
Nov 21 2012	Reply of petitioner Federal Trade Commission filed. (Distributed)
Dec 7 2012	Petition GRANTED. Justice Alito took no part in the consideration or decision of this petition.
Dec 20 2012	Consent to the filing of amicius curiae briefs, in support of either party or of neither party, received from counsel for the petitioner.
Jan 7 2013	SET FOR ARGUMENT ON Monday, March 25, 2013
Jan 10 2013	Proposal from counsel for respondent Par Pharmaceutical Companies, Inc. to lodge copies of a letter it filed with the FTC and Dept. of Justice pursuant to the MMA.
Jan 22 2013	Motion for leave to file Volume 2 of the joint appendix under seal filed by petitioner Federal Trade Commission.
Jan 22 2013	Joint appendix filed. (Volume 1 of 2) (Statement of costs received.)
Jan 22 2013	Brief of petitioner Federal Trade Commission filed.
Jan 24 2013	Record received from U.S.C.A. for 11th Circuit. (1 envelope).
Jan 28 2013	CIRCULATED.

Jan 28 2013 Brief amicus curiae of Knowledge Ecology International filed. (Distributed)

Jan 28 2013 Brief amicus curiae of Public Patent Foundation filed. (Distributed)

Jan 29 2013 Brief amici curiae of Louisiana Wholesale Drug Company, Inc., et al. filed. (Distributed)

Jan 29 2013 Brief amicus curiae of America's Health Insurance Plans filed. (Distributed)

Jan 29 2013 Brief amici curiae of New York, et al. filed. (Distributed)

Jan 29 2013 Brief amici curiae of 118 Law, Economics, and Business Professors, and the American Antitrust Institute filed. (Distributed)

Jan 29 2013 Brief amicus curiae of Apotex, Inc. filed. (Distributed)

Jan 29 2013 Brief amici curiae of AARP, et al. filed. (Distributed)

Jan 29 2013 Brief amicus curiae of Representative Henry A. Waxman filed. (Distributed)

Jan 29 2013 Brief amicus curiae of National Association of Chain Drug Stores filed. (Distributed)

Jan 30 2013 Motion DISTRIBUTED for Conference of February 15, 2013.

Feb 13 2013 Sealed record from U.S.D.C. for Northern District of Atlanta (1 envelope). The remainder of the record is electronic.

Feb 19 2013 Motion for leave to file Volume 2 of the joint appendix under seal GRANTED. Justice Alito took no part in the consideration or decision of this motion.

Feb 21 2013 Brief of respondent Solvay Pharmaceuticals, Inc. filed. (Distributed)

Feb 21 2013 Brief of respondents Par Pharmaceutical Companies, Inc. and Paddock Holdings, Inc filed. (Distributed)

Feb 21 2013 Brief of respondent Actavis, Inc. filed. (Distributed)

Feb 27 2013 Brief amicus curiae of National Association of Manufacturers filed. (Distributed)

Feb 28 2013 Brief amici curiae of Generic Manufacturers Upsher-Smith Laboratories, Inc., et al. filed. (Distributed)

Feb 28 2013 Brief amicus curiae of Enavail, LLC filed. (Distributed)

Feb 28 2013 Brief amicus curiae of Generic Pharmaceutical Association filed. (Distributed)

Feb 28 2013 Brief amici curiae of Bayer AG and Bayer Corp. filed. (Distributed)

Feb 28 2013 Brief amicus curiae of Shire PLC filed. (Distributed)

Feb 28 2013 Brief amicus curiae of New York Intellectual Property Law Association filed. (Distributed)

Feb 28 2013 Brief amicus curiae of Merck & Co., Inc. filed. (Distributed)

Feb 28 2013 Brief amicus curiae of Pharmaceutical Research and Manufacturers of America filed. (Distributed)

Feb 28 2013 Motion of Enavail, LLC for leave to participate in oral argument as amicus curiae and for divided argument filed.

Feb 28 2013 Brief amici curiae of Antitrust Economists filed. (Distributed)

Feb 28 2013 Brief amici curiae of Law Professors Gregory Dolin, Kent Bernard, et al. filed. (Distributed)

Feb 28 2013 Brief amicus curiae of American Intellectual Property Law Association filed. (Distributed)

Feb 28 2013 Brief amici curiae of Mediation and Negotiation Professionals filed. (Distributed)

Feb 28 2013 Brief amici curiae of David W. Opderbeck and Erik Lillquist filed. (Distributed)

Feb 28 2013 Brief amici curiae of Health and Economics Professors filed. (Distributed)

Feb 28 2013 Brief amicus curiae of Washington Legal Foundation filed. (Distributed)

Feb 28 2013	Brief amicus curiae of Intellectual Property Owners Association filed. (Distributed)
Mar 15 2013	Motion of Enavail, LLC for leave to participate in oral argument as amicus curiae and for divided argument DENIED. Justice Alito took no part in the consideration or decision of this motion.
Mar 18 2013	Reply of petitioner Federal Trade Commission filed. (Distributed)
Mar 21 2013	Motion to Unseal Volume II of the Joint Appendix filed by petitioner Federal Trade Commission. (Distributed)
Mar 21 2013	Motion DISTRIBUTED for Conference of March 22, 2013.
Mar 22 2013	Letter of March 21, 2013, from counsel for respondent Solvay Pharmaceuticals, Inc. received. (Distributed)
Mar 22 2013	Motion to unseal Volume II of the joint appendix GRANTED. Justice Alito took no part in the consideration or decision of this motion.
Mar 25 2013	Argued. For petitioner: Malcolm L. Stewart, Deputy Solicitor General, Department of Justice, Washington, D. C. For respondents: Jeffrey I. Weinberger, Los Angeles, Cal.

PETITION FOR WRIT OF CERTIORARI

RECORD AND BRIEFS

12-416

FILED
OCT 4 - 2012
OFFICE OF THE CLERK

No.

In the Supreme Court of the United States

FEDERAL TRADE COMMISSION, PETITIONER

v.

WATSON PHARMACEUTICALS, INC., ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Federal competition law generally prohibits an incumbent firm from agreeing to pay a potential competitor to stay out of the market. See *Palmer* v. *BRG of Ga., Inc.*, 498 U.S. 46, 49-50 (1990). This case concerns agreements between (1) the manufacturer of a brand-name drug on which the manufacturer assertedly holds a patent, and (2) potential generic competitors who, in response to patent-infringement litigation brought against them by the manufacturer, defended on the grounds that their products would not infringe the patent and that the patent was invalid. The patent litigation culminated in a settlement through which the seller of the brand-name drug agreed to pay its would-be generic competitors tens of millions of dollars annually, and those competitors agreed not to sell competing generic drugs for a number of years. Settlements containing that combination of terms are commonly known as "reverse payment" agreements. The question presented is as follows:

Whether reverse-payment agreements are per se lawful unless the underlying patent litigation was a sham or the patent was obtained by fraud (as the court below held), or instead are presumptively anticompetitive and unlawful (as the Third Circuit has held).

PARTIES TO THE PROCEEDING

The petitioner is the Federal Trade Commission.

Respondents are Watson Pharmaceuticals, Inc., Solvay Pharmaceuticals, Inc., Par Pharmaceutical Companies, Inc., and Paddock Laboratories, Inc.

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No.

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v.

WATSON PHARMACEUTICALS, INC., ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

The Solicitor General, on behalf of the Federal Trade Commission (FTC), respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Eleventh Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-36a) is reported at 677 F.3d 1298. The order of the district court (App., *infra*, 37a-61a) is reported at 687 F. Supp. 2d 1371.

JURISDICTION

The judgment of the court of appeals was entered on April 25, 2012. A petition for rehearing was denied on July 18, 2012 (App., *infra*, 62a-63a). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

Pertinent provisions of the Sherman Act, 15 U.S.C. 1 *et seq.*, the Federal Trade Commission Act, 15 U.S.C. 41 *et seq.*, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, and Title 35 of the United States Code are reproduced in the appendix to the petition (App., *infra*, 64a-122a).

STATEMENT

This case presents a recurring question of great economic importance that has divided the courts of appeals: how to judge the legality under the federal competition laws of a "reverse payment" agreement between a brand-name drug manufacturer and a potential generic competitor. In such an agreement, a patent holder (the brand-name manufacturer) agrees to pay a large sum of money to an accused infringer (its would-be competitor), and the competitor agrees that it will no longer challenge the patent and will not enter the market for a specified period of time. The court of appeals affirmed the dismissal of the FTC's complaint challenging two related reverse-payment agreements. App., *infra*, 28a. The court held that, "absent sham [patent] litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent," *i.e.*, so long as those exclusionary effects do not restrict generic competition more than would have a successful infringement suit. *Ibid.*

1. Under the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. 301 *et seq.*, the Food and Drug Administration (FDA) regulates the manufacture, sale,

and labeling of drugs.[1] To obtain FDA's approval to market a new drug, a manufacturer must submit a new drug application (NDA). 21 U.S.C. 355(b). The NDA must contain, *inter alia*, a statement of the drug's components, proposed labeling that describes the uses for which the new drug may be marketed, and scientific data and other information demonstrating that the drug is safe and effective as labeled. 21 U.S.C. 355(b)(1). A drug approved under the NDA process is often referred to as a "brand-name" drug. See generally *Caraco Pharm. Labs. Ltd.* v. *Novo Nordisk A/S*, 132 S. Ct. 1670, 1675-1676 (2012).

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585, known as the Hatch-Waxman Amendments. Those Amendments are "designed to speed the introduction of low-cost generic drugs to market," *Caraco*, 132 S. Ct. at 1676, both by establishing an abbreviated FDA approval process and by facilitating expeditious resolution of any patent-related disputes between brand-name and generic drug manufacturers. See, *e.g.*, H.R. Rep. No. 857, 98th Cong., 2d Sess., Pt. 1, at 14-17 (1984) (House Report); *id.* Pt. 2, at 5-6. The Hatch-Waxman Amendments provide that, after a brand-name drug's NDA has been approved, and subject to certain periods of NDA exclusivity (see 21 U.S.C. 355(j)(5)(F)), any manufacturer may seek approval to market a generic version by filing an abbreviated new drug application (ANDA) with FDA. See 21 U.S.C. 355(j). The ANDA process does not require the generic manufacturer to provide independent clinical evidence of safety or efficacy. Instead, the ANDA must generally

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[1] As used in this petition, "drug" refers to a drug, as defined in 21 U.S.C. 321(g)(1), regulated by FDA under 21 U.S.C. 355.

show, *inter alia*, that the generic drug has the same active ingredient(s) as, and is bioequivalent to, the brand-name drug to which the proposed generic will be compared. 21 U.S.C. 355(j)(2)(A)(ii) and (iv). See generally *Caraco*, 132 S. Ct. at 1676.

An ANDA must also explain how the generic drug can be marketed without infringing certain of the brand-name manufacturer's patents. See 21 U.S.C. 355(j)(2)(A)(vii)-(viii). Of particular relevance here, the generic manufacturer may file a "so-called paragraph IV certification," which states that a given patent asserted by the brand-name manufacturer to cover its brand-name drug "'is invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug.'" *Caraco*, 132 S. Ct. at 1677 (quoting 21 U.S.C. 355(j)(2)(A)(vii)(IV)). "The patent statute treats such a filing as itself an act of infringement, which gives the brand an immediate right to sue." *Ibid.* (citing 35 U.S.C. 271(e)(2)(A)). The Hatch-Waxman Amendments prescribe intricate rules specifying when FDA may and may not approve an ANDA while litigation is pending. See 21 U.S.C. 355(j)(5)(B). In general, however, the process enables the parties to obtain fairly definitive rulings on patent infringement and invalidity before the would-be generic manufacturer engages in the commercial sale of its product.

2. a. The agreements at issue here concern AndroGel®, a prescription gel used to treat hypogonadism, a medical condition involving the underproduction of testosterone associated with advancing age, certain cancers, diabetes, and HIV/AIDS, among other conditions. Second Amended Complaint (Complaint) ¶ 33. Besins Healthcare, S.A., developed AndroGel® and licensed the marketing rights in the United States to

respondent Solvay Pharmaceuticals, Inc. in 1995. *Id.* ¶ 32. FDA approved AndroGel® in February 2000, and the product had sales of more than $400 million in 2007. *Id.* ¶¶ 33, 34.

Although patents on the synthesized testosterone used in AndroGel® expired decades ago, in August 2000 Solvay applied for a patent on certain pharmaceutical formulations containing specified amounts of testosterone and certain other ingredients. Complaint ¶¶ 31, 38-39. In January 2003, the Patent and Trademark Office (PTO) issued a patent to Solvay. *Id.* ¶ 42. In May 2003, respondents Watson Pharmaceuticals, Inc. and Paddock Laboratories, Inc. submitted separate ANDAs to FDA seeking approval for generic versions of AndroGel®. *Id.* ¶ 44. The Watson and Paddock ANDAs each included a paragraph IV certification asserting that the applicant's generic product would not infringe Solvay's formulation patent and that the patent was invalid. *Ibid.* Shortly after Paddock submitted its ANDA, respondent Par Pharmaceutical Companies, Inc. agreed to partner with Paddock by sharing in Paddock's litigation costs and, eventually, promoting Paddock's generic version of AndroGel®. *Id.* ¶ 46.

In August 2003, Solvay sued Watson and Paddock for patent infringement. Complaint ¶ 47. During the ensuing patent litigation, Watson and Paddock amassed substantial evidence that their products would not infringe Solvay's formulation patent, and that the patent was invalid. *Id.* ¶¶ 86-89. By late 2005, Watson and Paddock had filed motions for summary judgment detailing much of this evidence. *Id.* ¶ 90.

In January 2006—at the expiration of the 30-month stay of FDA approval during patent litigation provided in 21 U.S.C. 355(j)(5)(B)(iii), and while the patent litiga-

tion was still pending—FDA approved Watson's ANDA. Complaint ¶ 52. Watson and Paddock/Par expected to begin selling their products no later than 2007. *Id.* ¶ 54. They predicted that prices for generic versions of AndroGel® would fall to as little as 15% or 25% of the price of Solvay's branded AndroGel®. *Id.* ¶¶ 50-51. Solvay anticipated losing approximately 90% of its AndroGel® sales within a year of the launch of a generic version, cutting its profits by $125 million a year. *Id.* ¶ 49.

Solvay internally evaluated its own and the generic firms' expected returns from continued litigation and settlement respectively. Complaint ¶ 57 & Exh. A. Solvay concluded that Watson and Paddock/Par might be willing to defer entry into the market, without receiving any monetary payment from Solvay, as part of a settlement of the patent litigation. *Ibid.* Solvay further concluded, however, that without a reverse payment, Watson and Paddock/Par would insist on an entry date that Solvay viewed as undesirably early. *Ibid.* In Solvay's view, a payment to its would-be competitors was necessary in order to secure their agreement not to compete before 2015 (the date by which Solvay anticipated shifting its customers to a new product with no generic equivalent). *Id.* ¶¶ 57, 63 & Exh. A.

Solvay's analysis was correct. Watson and Paddock/Par each insisted on receiving a payment in exchange for assenting to Solvay's preferred entry date. Complaint ¶¶ 61, 67, 70-71, 79. Solvay ultimately agreed to pay Watson an estimated $19 to 30 million annually, ostensibly for Watson to market AndroGel® to urologists. *Id.* ¶¶ 65-67. Solvay agreed to pay $2 million annually to Paddock and $10 million annually to Par, ostensibly for Paddock to serve as a back-up supplier of

AndroGel® and for Par to market the drug to primary care physicians. *Id.* ¶¶ 74-75. Even net of these payments, Solvay expected to make more profits from AndroGel® by maintaining its monopoly until 2015 than by continuing to litigate. *Id.* ¶ 58. Indeed, the agreements made economic sense only as a mechanism for Solvay to pay its nascent generic competitors to delay competing with it, because the marketing agreements and the back-up manufacturing deal had little value to Solvay. *Id.* ¶¶ 81-85.

3. The FTC filed suit under Section 5 of the Federal Trade Commission Act, 15 U.S.C. 45, to challenge respondents' agreements. The FTC asserted that the generic competitors' agreements not to compete with Solvay, in exchange for payments from Solvay, were unfair methods of competition. Complaint ¶¶ 106, 108 The FTC further alleged that Solvay had unlawfully extended its monopoly on AndroGel®, not on the basis of its patent, but by compensating its potential competitors. *Id.* ¶¶ 110-111. The FTC sought declarations that the agreements and Solvay's course of conduct were unlawful, and a permanent injunction against the parties' conduct pursuant to 15 U.S.C. 53(b). Complaint 43 (Prayer for Relief).

4. The district court dismissed the FTC's complaint for failure to state a claim. App., *infra*, 37a-61a. Relying on *Valley Drug Co.* v. *Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003), cert. denied, 543 U.S. 939 (2004), and *Schering-Plough Corp.* v. *FTC*, 402 F.3d 1056 (11th Cir. 2005), cert. denied, 548 U.S. 919 (2006), the court held the complaint insufficient because it "d[id] not allege that the settlements between the Defendants exceed the scope of [Solvay's] patent." App., *infra*, 48a. The court emphasized that the settle-

ments exclude generic versions of AndroGel® from the market only until August 31, 2015, which is "five years less exclusion than [Solvay's] patent" provides. *Ibid.* The court concluded that, absent allegations that the patent litigation itself was a sham, neither "the likelihood that [Solvay] could assert its claims in court and win" nor Solvay's promise to pay tens of millions of dollars annually to its potential competitors was a relevant consideration. *Id.* at 49a-52a.[2] The court also rejected, as inconsistent with circuit precedent, the FTC's contention that reverse-payment agreements should be deemed presumptively unlawful. *Id.* at 51a-52a.

5. The court of appeals affirmed. App., *infra*, 1a-36a. In its brief to the court of appeals, the FTC recognized that the Eleventh Circuit had already suggested on three occasions—in *Valley Drug*, *Schering-Plough*, and *Andrx Pharmaceuticals, Inc.* v. *Elan Corp.*, 421 F.3d 1227, 1234-1236 (2005)—that reverse-payment agreements were subject to very limited antitrust scrutiny. The FTC argued, however, that those decisions should be understood to permit a court to consider the likely exclusionary strength of the brand-name manufacturer's patent in evaluating the anticompetitive effect of a reverse-payment agreement. The FTC contended that, under such an analysis, the allegations of its complaint—in particular, that Solvay was not likely to prevail in its

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[2] The district court has since rejected, in private antitrust litigation challenging the reverse-payment agreements at issue here, the claim that Solvay's infringement suits were a sham, concluding as a matter of law that they were not objectively baseless. *In re Androgel Antitrust Litig. (No. II)*, No. 09-md-2084 Docket entry No. 830 (N.D. Ga. Sept. 28, 2012).

infringement suit—were sufficient to withstand a motion to dismiss. See FTC C.A. Br. 22-43.

The court of appeals rejected the FTC's interpretation of its earlier decisions. The court explained that, under its prior rulings, the brand-name manufacturer's patent made "traditional [antitrust] analysis * * * inappropriate." App., *infra*, 23a. Instead, the court held that, "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." *Id.* at 28a. The court of appeals stressed that, under its approach, "a patent's *actual* exclusionary power * * * does not count." *Id.* at 20a. Rather, the court explained, what matters is the patent's "*potential* exclusionary power," *ibid.*, which the court described as "the exclusionary rights appearing on the patent's face and not the underlying merits of the infringement claim." *Id.* at 26a n.8.

The court of appeals offered several reasons for rejecting an approach that would treat "a patent [as having] *no* exclusionary potential if its holder was not likely to win the underlying infringement suit." App., *infra*, 29a. First, the court stated that such an approach "equates a likely result (failure of an infringement claim) with an actual result, but it is simply not true that an infringement claim that is 'likely' to fail actually will fail." *Id.* at 30a. Second, the court expressed concern that, given the high stakes of patent litigation, "it obviously makes sense [for the patentee] to settle the infringement action if it is 'not likely to prevail,' even though [the patentee] may have a substantial (up to 49%) chance of winning." *Id.* at 31a. Third, the court adverted to the difficulty and unreliability of making "an

after-the-fact calculation of how 'likely' a patent holder was to succeed in a settled lawsuit if it had not been settled." *Id.* at 32a.

The FTC also urged that prior Eleventh Circuit decisions had misapplied general antitrust principles and had failed to heed congressional policy regarding patent disputes affecting generic drugs. It contended that, treating the issue *res nova*, reverse-payment agreements should be recognized as presumptively anticompetitive under the antitrust laws because "[i]n the absence of another explanation for them, * * * the patent holder is obtaining a greater degree of exclusion than it could have achieved without the payment * * * or with the expected outcome of litigation." FTC C.A. Br. 52; see *id.* at 43-56. The court of appeals acknowledged the FTC's fundamental position, App., *infra*, 4a, but adhered to its precedent.

6. The court of appeals denied the FTC's petition for rehearing en banc, which urged the court to revisit its precedent and treat reverse-payment agreements as presumptively unlawful. App., *infra*, 62a-63a.

REASONS FOR GRANTING THE PETITION

This case is a superior vehicle for resolving a circuit conflict on a well-defined legal issue of exceptional importance to the national economy. The court below, along with the Second and Federal Circuits, has held that federal competition law categorically permits reverse-payment agreements unless the underlying patent litigation was a sham or the patent was obtained by fraud. See App., *infra*, 1a-36a; *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005), amended, 466 F.3d 187 (2d Cir. 2006), cert. denied, 551 U.S. 1144 (2007); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) (*Cipro*),

cert. denied, 557 U.S. 920 (2009). The Third Circuit, by contrast, has recognized that such agreements closely resemble practices condemned as per se anticompetitive, and that court accordingly treats reverse-payment agreements as presumptively anticompetitive and unlawful. See *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (2012), petitions for cert. pending, No. 12-245 (filed Aug. 24, 2012) and No. 12-265 (filed Aug. 29, 2012).

The decision below is incorrect. In the Eleventh Circuit's view, a reverse-payment agreement is lawful unless it imposes greater restrictions on generic competition than would a judicial ruling that the brand-name manufacturer's patent is valid and infringed. That approach effectively equates a brand-name manufacturer's *allegation* of infringement with a judgment in the manufacturer's favor. But defendants often prevail in patent-infringement suits; the Hatch-Waxman Amendments are designed to facilitate judicial resolution of validity and infringement issues in the generic-drug context; and the federal antitrust laws flatly prohibit potential competitors from forming naked agreements not to compete. The anticompetitive potential of reverse-payment agreements—which are estimated to cost consumers billions of dollars annually—is sufficiently clear that they should be treated as presumptively unlawful under the federal competition laws.

The division of authority among lower courts has already led to inconsistent results in separate challenges to the same reverse-payment agreements. The circuit conflict is particularly untenable given the forum-shopping opportunities created by the flexible venue provisions that apply to review of FTC enforcement decisions and to private actions under the antitrust laws. This Court's intervention is therefore warranted to

resolve the conflict. This case is a superior vehicle for addressing the question presented because it is brought by an agency charged by Congress with challenging unfair methods of competition, and it comes to the Court in the straightforward posture of a final judgment following the dismissal of the FTC's complaint for declaratory and injunctive relief.

A. The Circuits Are In Acknowledged Conflict Over The Correct Antitrust Analysis Of Reverse-Payment Agreements

1. Three courts of appeals—the Eleventh Circuit below (App., *infra*, 28a & n.10), the Second Circuit (*Tamoxifen*, 466 F.3d at 212-213), and the Federal Circuit (*Cipro*, 544 F.3d at 1336), evaluate reverse-payment agreements under the so-called scope-of-the-patent approach. In those circuits, a reverse-payment agreement that excludes competition "within the scope of the exclusionary potential of the patent," App., *infra*, 28a, is categorically lawful under federal competition law, except when the underlying patent litigation was a sham or the patent was procured by fraud. The court below confirmed the rigidity of its approach by holding that its rule would insulate the reverse-payment agreements here from antitrust scrutiny even if the FTC proved its allegations that Solvay was not likely to prevail in its patent-infringement suit against its generic competitors. The court explained that the scope-of-the-patent approach "focus[es] on the potential exclusionary effect of the patent"—that is, the scope of the patent as asserted by the patentee in its patent-infringement complaint—and "not [on] the [patent's] likely exclusionary effect." *Id.* at 30a; see *id.* at 20a, 26a n.8. In substance, the scope-of-the-patent approach treats each reverse-payment agreement as valid so long as it does

not impose greater restrictions on generic competition than a successful infringement suit would have done. The practical effect of that approach is virtually to immunize reverse-payment agreements from antitrust scrutiny.

The Third Circuit, by contrast, has explicitly rejected the scope-of-the-patent rule. See *K-Dur*, 686 F.3d at 214-218. That court held instead that reverse-payment agreements are subject to a "quick look rule of reason analysis" under which "any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market [is] *prima facie* evidence of an unreasonable restraint of trade." *Id.* at 218. Under the Third Circuit's approach, that presumption of unlawfulness can "be rebutted by showing" either "that there is in fact no reverse payment because any money that changed hands was for something other than a delay," or "that the reverse payment offers a competitive benefit that could not have been achieved in the absence of a reverse payment" and thereby "increases competition." *Ibid.* Although the Sixth and D.C. Circuits have not adopted specific standards to determine the legality of reverse-payment agreements, they have likewise recognized the potential anticompetitive effects of similar arrangements. See *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 905-909 (6th Cir. 2003), cert. denied, 543 U.S. 939 (2004); *Andrx Pharms., Inc.* v. *Biovail Corp. Int'l*, 256 F.3d 799, 806-815 (D.C. Cir. 2001) (*Biovail*), cert. denied, 535 U.S. 931 (2002).

2. This divergence among the circuits has been outcome-determinative in prior cases challenging reverse-payment agreements. Antitrust defendants in the Second, Eleventh, and Federal Circuits have typically prevailed as a matter of law in cases involving a reverse-

payment agreement.[3] By contrast, the Third, Sixth, and D.C. Circuits have consistently ordered further proceedings.[4]

That divergence in outcomes traces directly to the circuits' different starting points. The scope-of-the-patent approach begins with the premise that reverse-payment agreements are lawful, and it considers only limited exceptions to that rule. Conversely, the "quick look" approach presumes that such agreements are anticompetitive, and considers the antitrust defendants' case in rebuttal. The contrast between the Third Circuit's decision in *K-Dur*, *supra*, and the Eleventh Circuit's decision in *Schering-Plough Corp.* v. *FTC*, 402 F.3d 1056 (2005), cert. denied, 548 U.S. 919 (2006), vividly illustrates the conflict. Although both those cases involved the same set of reverse-payment agreements, the two circuits applied contrasting legal rules to reach conflicting results.

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[3] See App., *infra*, 1a-36a; *Arkansas Carpenters Health & Welfare Fund* v. *Bayer AG*, 604 F.3d 98 (2d Cir. 2010), cert. denied, 131 S. Ct. 1606 (2011); *Cipro*, *supra*; *Tamoxifen*, *supra*; *Schering-Plough Corp.* v. *FTC*, 402 F.3d 1056 (11th Cir. 2005), cert. denied, 548 U.S. 919 (2006); see also *K-Dur*, 686 F.3d at 214 ("[N]o court applying the scope of the patent test has ever permitted a reverse payment antitrust case to go to trial."). But see *Andrx Pharms., Inc.* v. *Elan Corp.*, 421 F.3d 1227, 1234-1236 (11th Cir. 2005) (permitting an antitrust challenge to a settlement agreement between a brand-name drug manufacturer and a would-be generic competitor based on the generic competitor's anticompetitive agreement to create a bottleneck to FDA approval of other potential generic competitors' products); *Valley Drug Co.* v. *Geneva Pharms., Inc.*, 344 F.3d 1294, 1312 (11th Cir. 2003) (remanding for a determination whether "provisions of the [reverse-payment] [a]greements * * * have effects beyond the exclusionary effects of [the] patent"), cert. denied, 543 U.S. 939 (2004).

[4] See *K-Dur*, *supra*; *Cardizem*, *supra*; *Biovail*, *supra*.

3. This circuit split is particularly untenable because the sharp differences in circuit precedent transform the liberal venue rules that apply to private antitrust suits and to petitions for review of FTC decisions into open invitations to forum shopping. If the circuits' rules are left in place, private antitrust plaintiffs can be expected in the first instance to lay venue within the Third Circuit, which is feasible because drug manufacturers typically "may be found or transact[] business," 15 U.S.C. 22, in judicial districts within that circuit. By contrast, a drug manufacturer seeking judicial review of an administrative order of the FTC can be expected to lay venue in the Eleventh Circuit, as a place "where such * * * corporation * * * carries on business," 15 U.S.C. 45(c). The near certainty of facing judicial review in a circuit that applies the scope-of-the-patent approach has effectively disabled the FTC from proceeding administratively against any reverse-payment agreement. Resolution of the substantive issue of competition law that has divided the circuits therefore would not only secure the consistency of substantive law, but also ensure that outcomes are controlled by substantive legal rules and the facts of particular cases, rather than by the procedural tactics of the parties involved.[5]

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[5] At least two courts have stayed antitrust challenges to reverse-payment agreements pending this Court's action on petitions for writs of certiorari presenting the question of the correct approach to scrutinizing such agreements. See *King Drug Co. of Florence, Inc.* v. *Cephalon, Inc.*, No. 06-cv-1797 Docket entry No. 479 (E.D. Pa. Aug. 29, 2012); *In re Cipro Cases I & II*, No. S198616 Docket entry (Cal. Sept. 12, 2012).

B. The Question Presented Is Of Exceptional Importance

Reverse-payment agreements tend to support monopoly pricing of brand-name drugs by delaying the onset of generic competition, and they are increasingly common in the drug industry. Accordingly, the question presented is of exceptional importance to one of the largest commercial markets in the United States.

1. The 2011 domestic market for drugs totaled approximately $245 billion. See IMS Inst. for Healthcare Informatics, *The Use of Medicines in the United States: Review of 2011*, at 27 (Apr. 2012), http://www.imshealth.com/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/IHII_Medicines_in_U.S_Report_2011.pdf. A central purpose of the Hatch-Waxman Amendments was to manage increasing costs in that market by "mak[ing] available more low cost generic drugs" through a streamlined approval process. House Report, Pt. 1, at 14. Consistent with Congress's design, as generic competition sets in, the price for a generic drug settles, on average, at approximately 15% of the price charged for the brand-name drug before generic competition. See FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 8 (Jan. 2010) (*Pay-for-Delay Report*), http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf. At the same time, the brand-name manufacturer typically loses about 90% of its market share (by unit sales) to its generic competitors. *Ibid.* As a result, substantially lower costs are paid by a wide range of participants in the market—by individuals (who may pay for drugs out-of-pocket), by health-insurance companies (which reimburse the cost of prescription drugs), by employers (which pay health-insurance premiums), and by taxpayers (who support programs such as Medicare and Medicaid).

The speed with which generic competition arrives—and thus the point in time when these savings first accrue—often depends on the patent rights held by the brand-name manufacturer. Although the patent laws grant an inventor the right to exclude others from practicing an invention for a limited time, 35 U.S.C. 154, 271(a), a brand-name manufacturer's patent will prevent competition only from generic products that would infringe the patent, and only if the patent survives any challenges to its validity. The Hatch-Waxman Amendments recognize that a brand-name manufacturer's patents will not always satisfy those criteria, since they authorize the would-be generic competitor to certify that the patent in question "is invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug." 21 U.S.C. 355(j)(2)(A)(vii)(IV).

In particular, a generic competitor may be able to design its product to satisfy FDA regulations regarding generic drugs yet avoid infringing a patent that claims only particular features of the brand-name drug product (such as an inactive ingredient, or a coating that affects how the active ingredient is released into the body). See, *e.g.*, *Pharmacia & Upjohn Co.* v. *Mylan Pharms., Inc.*, 170 F.3d 1373, 1377-1379 (Fed. Cir. 1999) (finding non-infringement where the generic drug was designed to avoid a patent claiming an inactive ingredient); see generally *Caraco Pharm. Labs., Ltd.*, v. *Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012) (noting that drug "patents come in different varieties"); 21 C.F.R. 314.53. Some scholars have concluded that the patent portfolios of brand-name drug manufacturers have grown in recent years with the addition of patents that may be particularly susceptible to being avoided, in whole or in part, by generic competitors. See C. Scott Hemphill &

Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. Empirical Legal Stud. 613, 615, 619-623 (2011). And as for invalidity, a substantial fraction of fully litigated patent cases have, historically, resulted in a finding of patent invalidity. See John Allison & Mark Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 194, 205 (1998) (*Validity of Litigated Patents*) (finding that 46% of all litigated patents were declared invalid based on examination of all written, final validity decisions by district courts and the Federal Circuit between 1989 and 1996).

Overall, in cases litigated to decision, would-be generic competitors have prevailed three quarters of the time in paragraph IV patent litigation against brand-name manufacturers. See FTC, *Generic Drug Entry Prior to Patent Expiration* 10, 19-20 (July 2002) (*Generic Drug Entry*) (finding that generic competitors prevailed over brand-name manufacturers with respect to 73% of the drug products that were the subject of a court decision on paragraph IV patent litigation initiated between 1992 and 2000), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf; see also Paul Janicke & LiLan Ren, *Who Wins Patent Infringement Cases?*, 34 AIPLA Q.J. 1, 5 (2006) (finding that accused infringers had a 75% success rate in Federal Circuit decisions between 2002 and 2004 with a final ruling on drug-patent claims). Consumers have in turn reaped enormous benefits from successful challenges of that nature. See, *e.g.*, *Generic Pharmaceuticals: Marketplace Access and Consumer Issues: Hearing Before S. Commerce Comm.*, 107th Cong., 2d Sess. 56, 61 (2002) (Statement of Kathleen D. Jaeger, President & CEO, Generic Pharmaceutical Association) (estimating successful challenges to patents related to the widely used drugs Prozac, Zantac, Taxol,

and Platinol alone as saving consumers more than $9 billion).

2. If reverse-payment agreements are treated as presumptively lawful, such arrangements will be highly attractive to both brand-name manufacturers and their would-be generic competitors. Such agreements allow all parties to obtain greater profits from avoiding or delaying generic competition than they could obtain from litigating the patent case or settling it on other terms.

Standard economic theory predicts that a brand-name manufacturer's monopoly profits will greatly exceed the combined profits that the brand-name and generic manufacturers could earn if they competed against each other for sales of the same drug. All parties to the patent litigation therefore will be better off if they agree to delay competition and share the resulting profits. See 12 Herbert Hovenkamp, *Antitrust Law* ¶ 2046c, at 338 (3d ed. 2012) (*Antitrust Law*) ("In such cases a settlement agreement effectively 'preserves' the patent, thus giving the two firms the joint-maximizing, or monopoly, output."). Indeed, the continuing stream of monopoly profits is large enough to pay the generic competitors more than they could hope to earn if they entered the market at competitive prices, while leaving the brand-name manufacturer greater profits than it could earn in the face of generic competition. See C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1581-1582 (2006) (*Pharmaceutical Patent Settlement*).

3. In short, under the decision below, drug companies will have a substantial financial incentive to shift away from conduct that benefits consumers (generic

entry following the generic manufacturer's successful defense against a patent-infringement suit) toward conduct that harms consumers (preserving monopoly pricing through reverse-payment agreements). A large fraction of the drug market is susceptible to this influence. At the end of Fiscal Year 2008, an estimated $90 billion of brand-name drug sales were under threat from one or more ANDAs containing a paragraph IV certification, potentially setting the stage for a multiplicity of reverse-payment agreements. See *Pay-for-Delay Report* 9. The number of reverse-payment agreements settling paragraph IV patent litigation has grown markedly in the years since Congress first required drug manufacturers to notify the government of settlements of paragraph IV patent litigation. See Bureau of Competition, FTC, *Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in Fiscal Year 2011*, at 1-2 (2011),http://www.ftc.gov/os/2011/10/1110mmaagree.pdf; Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1111-1117, 117 Stat. 2461-2463 (21 U.S.C. 355 note) (requiring such notifications).

Reverse-payment agreements demonstrably delay the entry of generic competition, costing consumers billions of dollars each year. The average delay of generic entry following settlement of patent litigation with a reverse-payment agreement is nearly 17 months longer than the delay of generic entry agreed to following a settlement without a reverse payment. See *Pay-for-Delay Report* 2. That difference both signals the magnitude of the harm to consumers from such agreements and confirms the common-sense inference that

the payment from the brand-name manufacturer to its potential competitor purchases the competitor's agreement not to compete. Reverse-payment agreements impose costs on consumers and businesses sufficiently substantial to warrant this Court's review. See *ibid.*

C. The Court Of Appeals' Decision Is Incorrect

The scope-of-the-patent approach in general, and the decision of the court below in particular, reflect a misapplication of federal competition law. The Third Circuit's approach, which treats reverse-payment agreements as presumptively anticompetitive, reflects the appropriate balance between the competing interests implicated by such agreements. This Court should correct the Eleventh Circuit's error and remand the case to allow the FTC's suit to proceed under that approach.[6]

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[6] The view that reverse-payment settlements are presumptively anticompetitive is the longstanding position of the FTC, and it has been the position of the United States in recent briefs filed in the Second and Third Circuits, see note 8, *infra*. In three prior cases, in response to invitations from this Court, the United States has filed petition-stage briefs discussing the proper treatment of such agreements. See *Andrx Pharms., Inc.* v. *Kroger Co.*, 540 U.S. 1160 (2004) (Court invitation); *FTC* v. *Schering-Plough Corp.*, 546 U.S. 974 (2005) (same); *Joblove* v. *Barr Labs., Inc.*, 549 U.S. 1277 (2007) (same). In those briefs, the United States did not endorse the FTC's view that reverse-payment settlements are presumptively anticompetitive. The United States did contend, however, that the scope-of-the patent rule is an "insufficiently stringent standard" for determining the propriety of those settlements. U.S. Br. at 8, *Joblove*, *supra*; see *id.* at 12-15. The United States argued, albeit without advocating any specific test, that the antitrust inquiry should include an assessment of the likelihood that the brand-name manufacturer would have prevailed in the underlying infringement suit. See *id.* at 12 ("In determining whether the exclusionary effect of a settlement involving a reverse payment renders the settlement unreasonable and anti-

1. The correct approach, taken by the Third Circuit, is to treat reverse-payment agreements as presumptively anticompetitive. Such agreements most closely resemble agreements through which an incumbent firm pays a potential competitor to stay out of the market—a practice ordinarily condemned as a per se violation of Section 1 of the Sherman Act, 15 U.S.C. 1. See *Palmer* v. *BRG of Ga., Inc.*, 498 U.S. 46, 49-50 (1990). Such agreements between rivals are generally anticompetitive because they directly restrict output and raise price. See, *e.g.*, Dennis W. Carlton & Jeffrey M. Perloff, *Modern Industrial Organization* 123-125 (4th ed. 2005). This bedrock principle of competition law applies even if the would-be competitor's prospects of successful market entry were uncertain. See 12 *Antitrust Law* ¶ 2030b, at 220 ("[T]he law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition."); *United States* v. *Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir.) (en banc), cert. denied, 534 U.S. 952 (2001); *Engine Specialities, Inc.* v. *Bombardier Ltd.*, 605 F.2d 1, 9 (1st Cir. 1979), cert. denied, 446 U.S. 983 (1980).

The Third Circuit in *K-Dur* appropriately emphasized that its decision does not "limit[] the ability of the parties [in the Hatch-Waxman context] to reach settlements based on a negotiated entry date for marketing of the generic drug." 686 F.3d at 217-218. When the brand-name and generic manufacturers agree to a date

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competitive, a court at a minimum should take into account the relative likelihood of success of the parties' claims, viewed ex ante."); U.S. Br. at 11, *Schering-Plough*, *supra*. This Court denied certiorari in all three cases. See *Andrx Pharms., Inc.* v. *Kroger Co.*, 543 U.S. 939 (2004); *FTC* v. *Schering-Plough Corp.*, 548 U.S. 919 (2006); *Joblove* v. *Barr Labs., Inc.*, 551 U.S. 1144 (2007).

of entry before the date of patent expiration, the particular date chosen is likely to reflect the parties' assessment of their respective prospects of success in the infringement suit. At least in the aggregate, settlements of that character are unlikely to reduce the volume of generic competition below the level that would occur if all Hatch-Waxman infringement suits were litigated to judgment. The court in *K-Dur* explained that "the only settlements subject to antitrust scrutiny" under its decision "are those involving a reverse payment from the name brand manufacturer to the generic challenger." *Id.* at 218. Reverse-payment agreements raise particular concerns because, absent some other persuasive explanation, a reverse payment is most naturally understood as consideration for the generic manufacturer's agreement to delay market entry.

Even with respect to reverse-payment agreements, per se condemnation is not appropriate because it would foreclose consideration of legitimate efficiencies that could plausibly be claimed to flow from settlement of patent litigation. See *NCAA* v. *Board of Regents*, 468 U.S. 85, 103-104 (1984) (holding per se condemnation appropriate only if "the likelihood of anticompetitive conduct [is] so great as to render unjustified further examination of the challenged conduct"); cf. *McDermott, Inc.* v. *AmClyde*, 511 U.S. 202, 215 (1994) ("[P]ublic policy wisely encourages settlements [of legal disputes]."). Rather, a "so-called 'quick look' or 'truncated rule of reason' analysis" is appropriate because, in the first analysis, respondents "ha[ve] engaged in practices similar to those subject to per se treatment." *K-Dur*, 686 F.3d at 209 (emphasis omitted). Under that approach, the restraints embodied in reverse-payment agreements are presumed to be anticompetitive, and the

antitrust defendants—who, after all, have settled litigation against each other by agreeing not to compete—bear the burden of advancing "some countervailing procompetitive virtue." *FTC* v. *Indiana Fed'n of Dentists*, 476 U.S. 447, 459 (1986).

Under the "enquiry meet for the case" at hand, *California Dental Ass'n* v. *FTC*, 526 U.S. 756, 781 (1999), the FTC's complaint stated a claim upon which relief can be granted by alleging the existence and circumstances of a presumptively anticompetitive reverse-payment agreement. Nothing in the FTC's complaint provides a basis for inferring, at this stage of the litigation, the sort of procompetitive justifications that the Third Circuit hypothesized might overcome that presumption, see *K-Dur*, 686 F.3d at 218. Accordingly, the Eleventh Circuit erred in affirming the dismissal of the FTC's complaint.

2. The scope-of-the patent approach applied by the court below has most frequently been defended on three related rationales. None of those justifications is persuasive on its own terms, let alone sufficient to support the nearly categorical treatment of reverse-payment agreements as lawful.

First, courts endorsing the scope-of-the-patent approach have concluded that, because the core right conferred by a patent is the right to exclude competition, a reverse-payment agreement is not *unlawfully* anticompetitive so long as it permits generic entry on or before the date when the patent is scheduled to expire. See, *e.g.*, App., *infra*, 23a-24a; *Tamoxifen*, 466 F.3d at 201-202, 213-214; *Valley Drug*, 344 F.3d at 1304-1306. In effect, those courts assess (and discount) the anticompetitive potential of a reverse-payment agreement by comparing the level of generic competition it permits

to the level of competition that would have occurred if the infringement suit had been litigated to judgment and the patent holder had prevailed. But while a valid patent confers a right to exclude within its scope, 35 U.S.C. 154(a)(1), the possession of an untested patent does not result in the automatic exclusion of potential rivals. See *K-Dur*, 686 F.3d at 214-215. Instead, when a patentee seeks to enforce its patent, it bears the burden of proving that the accused product or process falls within the scope of the patent's claims as properly construed. See *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370, 374 (1996) ("Victory in an infringement suit requires a finding that the patent claim covers the alleged infringer's product or process.") (internal quotation marks omitted). And although a patentee enjoys a statutory presumption that its patent is valid, see 35 U.S.C. 282, that presumption is rebuttable, see *Microsoft Corp.* v. *i4i Ltd. P'ship*, 131 S. Ct. 2238, 2245 (2011); *Lear, Inc.* v. *Adkins*, 395 U.S. 653, 670 (1969), and patents are often held invalid despite it, see *Validity of Litigated Patents*, 26 AIPLA Q.J. at 205.

Thus, when a reverse-payment agreement provides for deferred entry of a generic competitor, "the exclusion is a consequence of the payment, not of the patent itself," and "nothing in the Patent Act justifies the exclusion payment." 12 *Antitrust Law* ¶ 2046c1, at 347. As explained above (see p. 22, *supra*), moreover, a potential competitor's agreement to forgo market entry in exchange for a payment is ordinarily unlawful per se, even if the prospect of entry was uncertain to begin with (*i.e.*, even if other forces might have produced the same result). The fact that a potential generic competitor *might* have been excluded from the market if the infringement suit had been litigated to judgment thus

does not mean that the same result can lawfully be achieved through an agreement between competitors.

A patent holder may enforce its patent through (non-sham) litigation without fear of antitrust consequences. See *Walker Process Equip., Inc.* v. *Food Mach. & Chem. Corp.*, 382 U.S. 172, 176-177 (1965); see also *Professional Real Estate Investors, Inc.* v. *Columbia Pictures*, 508 U.S. 49, 56-57 (1993). When a patentee chooses this protected avenue of enforcement, however, it faces the risk that it could lose. A patentee may instead choose the certainty of settlement over the risks of litigation. But private agreements that settle litigation, like all other private contracts, do not enjoy the antitrust immunity afforded to litigation itself. The scope-of-the-patent approach unjustifiably permits patentees to use collusive agreements to avoid the risk that patent litigation could lead to an unfavorable outcome, while simultaneously enjoying the protection from antitrust scrutiny that the patent laws afford to enforcement through litigation.

Second, courts that have adopted the scope-of-the-patent approach have emphasized the general public policy favoring voluntary settlement of litigation. See, *e.g.*, *Cipro*, 544 F.3d at 1333; *Tamoxifen*, 466 F.3d at 202-203; *Valley Drug*, 344 F.3d at 1308. But settlement of litigation is not an unalloyed good; parties to a reverse-payment agreement can claim that mantle only by pointing to how "resolution of the case will benefit the public." *Tamoxifen*, 466 F.3d at 202 (citation omitted). Although reverse-payment agreements (like all settlements) conserve judicial resources, there are significant countervailing considerations in the patent context.

Judicial resolution of challenges to patent validity is a public good, see *K-Dur*, 686 F.3d at 215 (citing *Cardinal*

Chem. Co. v. *Morton Int'l Inc.*, 508 U.S. 83, 100-101 (1993)), as is judicial construction of patent claims in connection with litigation over infringement. "It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly." *Lear*, 395 U.S. at 663-664 (quoting *Pope Mfg. Co.* v. *Gormully*, 144 U.S. 224, 234 (1892)). Those considerations have particular force in the context of the Hatch-Waxman Amendments, which specifically contemplate the possibility that brand-name manufacturers' patents may be invalid or not infringed, and which were designed to facilitate efficient resolution of patent disputes to prevent uncertainty on those issues from obstructing the entry of generic competition. See *K-Dur*, 686 F.3d at 217; *Pharmaceutical Patent Settlement*, 81 N.Y.U. L. Rev. at 1614 (explaining how reverse-payment agreements undermine the plan of the Hatch-Waxman Amendments).

In any event, the Third Circuit's approach neither precludes nor treats as presumptively anticompetitive all voluntary settlements of patent-infringement suits between brand-name and generic drug manufacturers. To the contrary, the court in *K-Dur* expressly limited its holding to settlements "involving a reverse payment from the name brand manufacturer to the generic challenger." 686 F.3d at 218; see pp. 22-23, *supra*. Payments from the plaintiff to the defendant are scarcely an essential or traditional feature of settlement practice—to the contrary, they appear to be largely unknown outside the Hatch-Waxman context. Indeed, even in the Hatch-Waxman setting, "[d]ata analyzed by the FTC suggest that [the Third Circuit's rule] will

leave the vast majority of pharmaceutical patent settlements unaffected." *K-Dur*, 686 F.3d at 218.

Third, courts favoring the scope-of-the-patent approach have expressed the view that "reverse payments are particularly to be expected in the drug-patent context because the Hatch-Waxman [Amendments] created an environment that encourages them." *Tamoxifen*, 466 F.3d at 206; see *Schering-Plough*, 402 F.3d at 1074. But the competition laws exist precisely to counteract commercial "environment[s] that encourage[]" collusive and anticompetitive behavior. Observations about the opportunities and incentives for anticompetitive behavior that the Hatch-Waxman Amendments may create no more justify reverse-payment agreements than "the age-old cry of ruinous competition and competitive evils [is] a defense to price-fixing conspiracies," *United States* v. *Socony-Vacuum Oil Co.*, 310 U.S. 150, 221 (1940). Firms agree to restrain trade because it is rational—if socially harmful—for them to do so.

In assessing the antitrust status of reverse-payment agreements, moreover, it is important to understand *why* such agreements are attractive to the settling parties. When they select the date on which generic entry will be permitted under their settlement, the brand-name and generic manufacturers are not simply deciding how a fixed pool of profits will be divided between them. Rather, they are deciding how large the total pool will be, since the brand-name's profits during a year of market exclusivity will be greater than the combined profits of the brand-name and the generic manufacturers during a year when the two compete. See p. 19, *supra*. Thus, the later the date of generic entry, the greater the total profits of the brand-name and generic manufacturers taken together. Of course, if

the additional increment of profits were captured entirely by the brand-name manufacturer, the prospect of greater total revenues would provide no incentive for the generic to agree to later entry. In substance, the reverse payment is a mechanism for inducing the generic manufacturer to accept a reduction in its own drug sales in order to enhance the overall welfare of the combination. That co-option of potential competitors is at the very core of what the federal antitrust laws prohibit.

D. This Case Is A Superior Vehicle For Addressing the Question Presented

Also pending before this Court are petitions for writs of certiorari seeking review of the Third Circuit's judgment in *K-Dur*. See *Merck & Co.* v. *Louisiana Wholesale Drug Co.*, No. 12-245 (filed Aug. 24, 2012); *Upsher-Smith Labs., Inc.* v. *Louisiana Wholesale Drug Co*, No. 12-265 (filed Aug. 29, 2012). Although those petitions would be adequate vehicles for deciding the question presented, this petition offers a vehicle that is superior in several respects.[7]

First, *K-Dur* is a private class action, while this case is brought by a federal agency charged by Congress with challenging unfair methods of competition, see 15 U.S.C. 45, and responsible for reviewing agreements settling litigation under the Hatch-Waxman Amendments, see p. 20, *supra*. The FTC has challenged several reverse-payment agreements. See Health Care Division, FTC, *Overview of FTC Antitrust Actions in Pharmaceutical Services and Products* 13-19 (June 2012) (discussing activity), http://www.ftc.gov/bc/

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[7] We are providing copies of this petition to counsel for the parties in Nos. 12-245 and 12-265.

healthcare/antitrust/rxupdate.pdf. And in suits between private parties, the United States and the FTC have often participated as amici curiae in this Court and in the courts of appeals.[8] The Court would benefit from the experienced presentation that the FTC, represented by the Solicitor General, would offer as a party.

Second, the court of appeals below affirmed the grant of a motion to dismiss the FTC's complaint, while the *K-Dur* court reversed the grant of motions for summary judgment. This case thus arrives with a simpler record and on a final judgment, while the *K-Dur* petitions are interlocutory and burdened by a complex record. The disadvantages of taking up *K-Dur* are not merely theoretical. The *K-Dur* record presents unresolved collateral or subsidiary issues that could complicate this Court's deliberations or limit the scope of its holding.

In particular, the parties in *K-Dur* dispute whether the monetary consideration there was paid in exchange for delayed entry by one of the potential generic competitors, or was instead compensation for a license to an unrelated drug product. *K-Dur*, 686 F.3d at 205-206. Although the Third Circuit (appropriately in our view) did not address that issue, the Eleventh Circuit in *Schering-Plough* thought there was "overwhelming evidence" that the payment in question was for an

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[8] See U.S. Br., *K-Dur*, *supra* (No. 10-2077) (filed May 18, 2011); FTC Br., *ibid.* (filed May 18, 2011); U.S. Br., *Arkansas Carpenters Health & Welfare Fund* v. *Bayer AG*, 604 F.3d 98 (2d Cir. 2010) (No. 05-2851) (filed July 7, 2009, at court's invitation); U.S. Br., *ibid.* (filed June 4, 2010, on petition for rehearing); FTC Br., *ibid.* (filed June 10, 2010, on petition for rehearing); U.S. Br., *Joblove* v. *Barr Labs., Inc.*, 551 U.S. 1144 (2007) (No. 06-830) (filed May 23, 2007); U.S. Br., *FTC* v. *Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273) (filed May 17, 2006); U.S. Br., *Andrx Pharms., Inc.* v. *Kroger Co.*, 543 U.S. 939 (2004) (No. 03-779) (filed July 9, 2004).

unrelated product. 402 F.3d at 1070-1071. Under that view of the evidence, one of the manufacturers in *K-Dur* would be exonerated even under the legal standard that the Third Circuit adopted. See 686 F.3d at 218. No such concern is present in this case because, to the extent Solvay's generic competitors are providing services of value in exchange for Solvay's payment, they are doing so in support of the monopoly that their agreements not to compete helped to preserve. See Complaint ¶¶ 60-66, 72-77. In addition, the parties in *K-Dur* have addressed at length complex matters of chemistry and patent doctrine, in a dispute over whether Schering's generic competitors' products would have infringed its patent. See Appellants Br. 54-66, *K-Dur*, *supra* (No. 10-2077); Appellees Br. 55-80, *ibid.* No such complexity is present on the FTC's pleading here.

Third, the *K-Dur* plaintiffs seek only retrospective damages relief (because the underlying patent and reverse-payment agreements expired years ago, see *K-Dur*, 686 F.3d at 218-219), while here the FTC seeks only declaratory and prospective injunctive relief (principally against reverse-payment agreements that, by their terms, will remain in force until 2015, see App., *infra*, 12a). That makes this case the more attractive vehicle because whatever uncertainties may arise in fixing the damages caused by a reverse-payment agreement—a question no court of appeals has confronted or passed upon—the FTC unquestionably will be entitled to the remedy of an injunction if it proves that the reverse-payment agreements here are unfair methods of competition. Cf. *Blue Cross & Blue Shield United* v. *Marshfield Clinic*, 152 F.3d 588, 591 (7th Cir. 1998) ("Even though * * * [the antitrust plaintiff] has failed to come up with evidence that would authorize an award

of damages * * * , this does not justify withholding an injunction—rather the contrary."), cert. denied, 525 U.S. 1071 (1999).

Fourth, although both this case (see Complaint ¶¶ 86-87) and *K-Dur* (see 686 F.3d at 205) concern reverse-payment agreements made to settle patent litigation in which the generic competitors had strong arguments that their products did not infringe the brand-name manufacturer's patent, the antitrust plaintiffs in *K-Dur* have not relied on claims of patent invalidity in the underlying patent litigation, while the FTC has done so (see Complaint ¶¶ 88-89). The antitrust plaintiffs in *K-Dur* have argued, in part, for an antitrust analysis that distinguishes between invalidity and noninfringement defenses in the underlying patent litigation, in view of the fact that an issued patent is presumed valid, see p. 25, *supra*, but is not similarly presumed to be infringed. See Appellants Br. 35-38, *K-Dur*, *supra*. We do not endorse such a distinction (and no court of appeals has given dispositive effect to such a distinction). Granting certiorari in this case, however, would ensure that the Court can consider the proper antitrust analysis for cases in which the generic manufacturer has contested patent validity as well as for cases in which it has contested infringement.

As against these advantages, this case has no significant defects as a vehicle for addressing the question presented. The Court should therefore grant this petition for a writ of certiorari. The petitions for writs of certiorari in Nos. 12-245 and 12-265 could then be held pending resolution of this case. In the alternative, if the Court believes it would benefit from briefing on the factual record in *K-Dur*, it could grant all the pend-

ing petitions and consolidate the cases, allotting additional time for oral argument as appropriate.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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OCTOBER 2012

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 10-12729

D.C. DOCKET NO. 1:09-CV-00955-TWT

FEDERAL TRADE COMMISSION,
PLAINTIFF-COUNTER DEFENDANT-APPELLANT

v.

WATSON PHARMACEUTICALS, INC., SOLVAY PHARMACEUTICALS, INC., DEFENDANTS-APPELLEES

PAR PHARMACEUTICAL COMPANIES, INC.,
PADDOCK LABORATORIES, INC.,
DEFENDANTS-COUNTER CLAIMANTS-APPELLEES

Apr. 25, 2012

Appeal From The United States District Court
For The Northern District Of Georgia

Before: CARNES, KRAVITCH, and FARRIS,* Circuit Judges.

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* Honorable Jerome Farris, United States Circuit Judge for the Ninth Circuit, sitting by designation.

CARNES, Circuit Judge:

The system of developing new drugs in this country exemplifies the maxims "no risk, no reward" and "more risk, more reward." Developing new drugs is a risky, lengthy, and costly endeavor, but it also can be highly lucrative. Only one in every 5,000 medicines tested for the potential to treat illness is eventually approved for patient use, and studies estimate that developing a new drug takes 10 to 15 years and costs more than $1.3 billion.[1] No rational actor would take that kind of a risk over that period of time without the prospect of a big reward. The reward, if any, comes when the drug is approved and patented, giving the pioneer or "brand name" company that developed it a monopoly over the sale of the new drug for the life of the patent. The pioneer company can then exploit the patent monopoly by charging higher prices than it could if competitors were allowed to sell bioequivalent or "generic" versions of the drug. In that manner, the pioneer company is usually able to recoup its investment and gain a profit, sometimes a super-sized one.

Another maxim might also apply to the patent monopoly of drug pioneers: "more money, more problems." The huge profits that new drugs can bring frequently attract competitors in the form of generic drug manufacturers that challenge or try to circum-

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[1] Bret Dickey, Jonathan Orszag & Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 Annals Health L. 367, 369 & n.10 (2010).

vent the pioneer's monopoly in the market. Patent litigation often results, threatening the pioneer's monopoly and profits. Instead of rolling the dice and risking their monopoly profits in the infamously costly and notoriously unpredictable process of patent litigation, many patent-holding companies choose to settle lawsuits in order to preserve their patents and keep the monopoly profits flowing.

This case involves a type of patent litigation settlement known as a "pay for delay" or "reverse payment" agreement. In this type of settlement, a patent holder pays the allegedly infringing generic drug company to delay entering the market until a specified date, thereby protecting the patent monopoly against a judgment that the patent is invalid or would not be infringed by the generic competitor. This case began when the Federal Trade Commission filed a complaint in district court alleging that the reverse payment settlements between the holder of a drug patent and two generic manufacturers of the drug are unfair restraints on trade that violate federal antitrust laws. The FTC claims that the settlements are simply tools that the three manufacturers used to avoid a judgment that the patent was invalid or would not be infringed by the generics, thereby protecting monopoly profits that the companies divvied up by means of payments from the patent holder to the generic manufacturers. The key allegation in the FTC's complaint is that the patent holder was "not likely to prevail" in the infringement actions that it brought against the generic manufacturers and then settled. According to the

FTC, the reverse payment settlements unlawfully protected or preserved a monopoly that likely was invalid and that should not be shielded from antitrust attack.

The drug companies counter that, far from being devices designed to dodge antitrust restrictions, reverse payment settlements are simply a way that patent holders protect and maintain the lawful exclusionary rights patent law grants them. *Cf. Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177, 86 S. Ct. 347, 350 (1965) ("A patent . . . is an exception to the general rule against monopolies . . . ." (quotation marks omitted)); *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816, 65 S. Ct. 993, 998 (1945) (same). They say that punishing a patent holder for paying a potential competitor to stay out of the market as part of a settlement agreement would penalize precisely what patents are designed to permit: the exclusion of competition. That erosion of patent rights, the drug companies argue, would weaken incentives for investing in drug development, which would reduce the number of life-saving or life-enhancing innovations that benefit consumers.

The FTC would like us to hold that reverse payment settlements, like the ones in this case, are presumptively unlawful restraints of trade. It argues that such settlements allow brand name and generic drug companies to be partners in unlawful monopolies. Monopoly profits, the FTC says, will typically exceed the sum of the individual profits that the drug companies

could make by competing against each other. So even if the generic drug company is likely to win the infringement suit, it has a strong economic incentive to drop its lawsuit in exchange for a share of the brand name company's monopoly profits.[2] Viewed this way, a reverse payment settlement ending patent litigation is a "win-win" for both companies. The brand name drug company maintains its monopoly by enforcing a patent that may be invalid, and the generic drug company makes more money under the settlement than it could have earned by competing in a market free of the patent's restraints. While the drug companies are the big winners in this scenario, consumers are the big losers; they continue paying monopoly prices for the

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[2] The FTC's brief offers this explanation of the economic incentives involved:

> According to a study conducted by the FTC of the industry as a whole . . . , a branded manufacturer typically loses about 90 percent of its unit sales over the course of generic entry. While generic entrants gain that unit volume, they do not gain all the revenues lost by the branded manufacturer because, as generic competition sets in, the price falls, on average, to about 15 percent of what the branded manufacturer was charging. Thus, a branded manufacturer can expect that, if a drug is earning $1 billion a year before generic entry, the manufacturer will only earn about $100 million a year once generic competition has matured, and all the generic companies put together will only earn about $135 million a year (90% x 15% x $1 billion), thus leaving approximately $765 million a year for the public through the benefits of competition. The parties have a strong economic incentive to avoid that result.

Appellant Br. 33-34 (footnotes omitted).

drug even though the patent creating the monopoly is likely invalid or would not be infringed by generic competition. The FTC estimates that reverse payment settlements cost consumers about $3.5 billion per year in the form of higher drug prices.

I.

The usual protocol in opinions is to put the facts and procedural history of the case before a discussion of the applicable statutes, but in this case the facts make more sense after a discussion of the statutory process for introducing new drugs to the market.

No one can legally market or sell a new drug in the United States without first gaining the approval of the Food and Drug Administration. *See* 21 U.S.C. § 355(a). The particular pathway to approval depends largely on the type of drug involved. One pathway is for pioneer drugs, which are ones that have never before received FDA approval. To initiate that approval process, an applicant files a New Drug Application. *See id.* The NDA must contain detailed information about the drug, including its chemical composition, "full reports of investigations" about its safety and efficacy, descriptions of its production and packaging processes, and proposed labeling language. *Id.* § 355(b)(1). An NDA applicant must also provide the FDA with "the patent number and the expiration date of any patent" that a generic manufacturer would infringe by making or selling the applicant's drug. *Id.*; *see also* 21 C.F.R. § 314.53(b). If the FDA approves the NDA, it publishes the drug and patent information in a book called "Approved Drug Products

with Therapeutic Equivalence and Evaluations," commonly referred to as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A); *see also Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, No. 10-844, 2012 WL 1288732, at *5 (U.S. Apr. 17, 2012). The pioneer company may then market and sell the drug.

A more streamlined pathway to approval is reserved for generic versions of pioneer drugs that the FDA has already approved and listed in the Orange Book. To begin the generic drug approval process, an applicant files an Abbreviated New Drug Application. *See* 21 U.S.C. § 355(j). The ANDA allows an applicant "to piggyback on the safety and efficacy studies conducted for the pioneer drug" and thereby gain FDA approval by establishing that the generic drug is chemically identical to a pioneer drug already listed in the Orange Book. *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1296 (11th Cir. 2003); see 21 U.S.C. § 355(j)(2)(A); *Caraco Pharm. Labs.*, 2012 WL 1288732, at *5 ("Rather than providing independent evidence of safety and efficacy, the typical ANDA shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug.").

An ANDA that piggybacks on a drug listed in the Orange Book must make one of four "paragraph certifications" with respect to any patents affiliated with the listed drug. It must certify that: (I) no patent information for the brand name drug has been filed with the FDA; (II) the patent has expired; (III) the patent will expire on a specifically identified date;

or (IV) the "patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii).

It matters which certification is made. If the applicant certifies under paragraphs I or II, the FDA reviews the ANDA and may approve it. *See id.* § 355(j)(5)(B)(i). If the applicant certifies under paragraph III, however, the FDA will not approve the application until the patent for the listed drug has expired. *See id.* § 355(j)(5)(B)(ii).

If the applicant certifies under paragraph IV, things get complicated. The ANDA applicant must send notice to the patent holder of its position that the patent listed in the Orange Book is invalid or will not be infringed by the applicant's generic drug. *See id.* § 355(j)(2)(B). The patent holder then has 45 days to file an infringement lawsuit against the ANDA applicant. *Id.* § 355(j)(5)(B)(iii); *cf.* 35 U.S.C. § 271(e)(2)(A) (making it a constructive act of infringement to file a paragraph IV certification); *Caraco Pharm. Labs.*, 2012 WL 1288732, at *6 ("Filing a paragraph IV certification means provoking litigation."). If the patent holder does not sue within that time frame, the FDA proceeds with the ANDA approval process. 21 U.S.C. § 355(j)(5)(B)(iii). If a suit is timely filed, however, the FDA stays the ANDA approval process for 30 months to allow the parties or a court to resolve the infringement dispute. *Id.* If, during that 30-month stay, a court decides that the patent is invalid or not infringed, the FDA's

approval of the ANDA, if any, is effective on the date that the court enters its judgment. *Id.* § 355(j)(5)(B)(iii)(I)(aa).

Federal law encourages generic drug manufacturers to file paragraph IV certifications. The first ANDA applicant making a paragraph IV certification that receives FDA approval is granted a 180-day "exclusivity period" during which the FDA postpones its approval process for other ANDA applications for generic versions of the same Orange Book listed drug. *Id.* § 355(j)(5)(B)(iv). That exclusivity period begins to run "after the date of the first commercial marketing of the [generic] drug." *Id.* § 355(j)(5)(B)(iv)(I); *see also* 21 C.F.R. § 314.107(c)(1). As a result, the first generic manufacturer to make a paragraph IV certification could receive a 180-day head start to compete with the pioneer drug, which is "a significant incentive for generic manufacturers to challenge weak or narrow drug patents." *Valley Drug*, 344 F.3d at 1298.

II.

With that statutory approval process in mind, we turn to the facts of this case. Because this appeal arises from the district court's Rule 12(b)(6) dismissal of the FTC's complaint for failure to state a claim, we accept as true all of the factual allegations in that complaint. *Thaeter v. Palm Beach Cnty. Sheriff's Office*, 449 F.3d 1342, 1352 (11th Cir. 2006).

A.

Besins Healthcare, S.A., developed the prescription drug AndroGel, a topical gel that treats the symptoms

of low testosterone in men. Chemicals in the gel gradually penetrate the skin and enter the bloodstream, providing a sustained release of synthetic testosterone. In August 1995, Besins granted Solvay Pharmaceuticals, Inc., a license to sell AndroGel in the United States and agreed to provide a commercial supply of the drug if the FDA approved it for sale. Solvay filed an NDA for AndroGel in April 1999, which the FDA approved in February 2000. Solvay then began marketing and selling the drug with great success. Between 2000 and 2007, revenue from the sale of AndroGel in the United States exceeded $1.8 billion, far more than it cost to develop the drug.

Shortly after the FDA approved AndroGel, Solvay filed a patent application with the Patent and Trademark Office. A prior patent covering the synthetic testosterone used in AndroGel had expired decades earlier, but Solvay's application sought patent protection for a particular gel formulation of it. The Patent and Trademark Office granted Solvay's application on January 7, 2003, and jointly awarded Solvay and Besins Patent Number 6,503,894 ("the '894 patent"), which expires in August 2020. Within 30 days of being granted the patent, Solvay asked the FDA to include the '894 patent information in the Orange Book alongside the AndroGel listing. *Cf.* 21 U.S.C. § 355(c)(2) (requiring successful NDA applicants to inform the FDA within 30 days of receiving a new patent for a listed drug).

Other drug manufacturers soon developed generic versions of AndroGel. Two of those companies, Wat-

son Pharmaceuticals, Inc. and Paddock Laboratories, Inc., filed ANDAs with the FDA in May 2003. Watson was the first to file its ANDA, which made it eligible for the 180-day exclusivity period under 21 U.S.C. § 355(j)(5)(B)(iv). Both companies made paragraph IV certifications, claiming that their generic AndroGel products did not infringe on the '894 patent or that the patent was invalid. Within the relevant 45-day window, *id.* § 355(j)(5)(B)(iii), Solvay filed in federal district court a patent infringement lawsuit against Watson and Paddock.[3] That filing triggered the 30-month stay of the FDA's approval process for Watson's and Paddock's generic versions of AndroGel. *See id.* The stay was set to expire in January 2006.

The parties litigated the infringement action for the next few years. To spread the risks and costs of litigation, Paddock partnered with Par Pharmaceutical Companies, Inc., which agreed to share the costs of litigation with Paddock in exchange for part of the potential profits from Paddock's generic AndroGel product if that product gained FDA approval. After conducting discovery, Watson and Par/Paddock, the defendants in the patent infringement lawsuit, filed motions for summary judgment on the validity of the '894 patent. Those motions were fully briefed and ready for decision when the statutorily imposed 30-month stay on the FDA's approval process for Watson's ANDA ended in January 2006. The FDA approved Watson's generic AndroGel product that same month.

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[3] Besins filed a separate lawsuit against Watson and Paddock, but the outcome of that case is not relevant to this appeal.

As a result, Solvay was facing the possibility of losng its monopoly in the AndroGel market in early 2006. f the district court granted Watson's motion for summary judgment either on the ground that the '894 patent was invalid or that it would not be infringed by .he generic drugs, Watson could immediately flood the narket with generic versions of AndroGel without fear of being found to have violated Solvay's patent (unless :he district court's decision was overturned on appeal). *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I)(aa). Watson forecast that its generic version of AndroGel would sell for about 25% of the price of branded AndroGel, which could decrease the sales of branded AndroGel by 90% and cut Solvay's profits by $125 million per year. A lot was riding on the outcome of the patent litigation.

Before the district court ruled on Watson's and Par/Paddock's motions for summary judgment, and before any generic AndroGel was brought to market, the parties resolved their patent dispute with several settlement agreements. Under the terms of the settlements, Watson, Par, and Paddock agreed not to market generic versions of AndroGel until August 31, 2015, unless another manufacturer launched one before then. In addition, Watson agreed to promote branded AndroGel to urologists, and Par agreed to promote it to primary care doctors. Par also agreed to serve as a backup manufacturer for branded AndroGel but assigned that part of the agreement to Paddock.

For its part, Solvay agreed to pay Par/Paddock $10 million per year for six years and an additional $2 million per year for the backup manufacturing assistance.

Solvay also agreed to share some of its AndroGel profits with Watson through September 2015, projecting that those payments would be between $19 million and $30 million per year. After finalizing the agreements, all of the parties—Solvay, Watson, Par, and Paddock—filed in district court a stipulation of dismissal terminating the patent infringement lawsuit.

B.

After the settlement agreements ending the patent litigation were reported to the FTC as required by 21 U.S.C. § 355 note (2003) (Federal Trade Commission Review), the FTC filed an antitrust lawsuit against Solvay, Watson, Par, and Paddock. That lawsuit was then transferred to the Northern District of Georgia, which is where the parties had litigated the patent infringement claims. The FTC then filed an amended complaint against all four drug companies.[4]

The FTC's amended complaint claimed that the settlement agreements, in which Solvay promised to pay Watson and Par/Paddock in exchange for those companies not selling generic AndroGel until 2015, are unlawful agreements not to compete in violation of Section 5(a) of the Federal Trade Commission Act. 15 U.S.C. § 45(a)(1) (banning "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce").

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[4] Two other sets of plaintiffs—direct and indirect purchasers of AndroGel—joined the FTC in the district court and made a variety of state law claims. None of those plaintiffs joined the FTC in this appeal, and their claims are not before us.

It alleged that the settlement agreements were attempts to "defer" generic competition with branded AndroGel by postponing the entry date of the generic drugs, thereby maintaining Solvay's monopoly and allowing the parties to share monopoly profits "at the expense of the consumer savings that would result from price competition."

The lynchpin of the FTC's complaint is its allegation that Solvay probably would have lost the underlying patent infringement action—that is, Watson and Par/Paddock had a strong case that the '894 patent did not bar their entry into the generic AndroGel market. More specifically, the complaint alleges that "Solvay was *not likely to prevail*" in the patent litigation because "Watson and Par/Paddock developed persuasive arguments and amassed substantial evidence that their generic products did not infringe the ['894] patent and that the patent was invalid and/or unenforceable" (emphasis added). According to the FTC, because the '894 patent "was unlikely to prevent generic entry," Solvay's reverse payments to the generic drug producers continued and extended a monopoly that the patent laws did not authorize. By doing that, it argues, the reverse payment agreements unlawfully restrain competition.

The four defendants moved to dismiss the FTC's complaint under Rule 12(b)(6), arguing that this Court's precedent immunizes reverse payment settlements from antitrust attack unless a settlement "imposes an exclusion greater than that contained in the patent at issue." Because the FTC had not alleged

the settlements did that, the defendants argued, the complaint failed to state a claim on which relief could be granted. The district court agreed with the defendants, concluded that the FTC did "not allege that the settlements exceed the scope of the '894 patent," and granted the defendants' motion to dismiss. The FTC then filed this appeal, contending that it had sufficiently pleaded an antitrust claim by alleging that the parties had entered into the settlement agreements even though Solvay was "not likely to prevail" in the infringement actions against the generic producers.

III.

"We review *de novo* the district court's grant of a motion to dismiss under 12(b)(6) for failure to state a claim . . . ." *Ironworkers Local Union 68 v. AstraZeneca Pharm., LP*, 634 F.3d 1352, 1359 (11th Cir. 2011) (quotation marks omitted). In doing so, we accept the allegations in the complaint as true and construe them "in the light most favorable to the plaintiff." *Clark v. Riley*, 595 F.3d 1258, 1264 (11th Cir. 2010) (quotation marks omitted). "A complaint must state a plausible claim for relief, and '[a] claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Sinaltrainal v. Coca-Cola Co.*, 578 F.3d 1252, 1261 (11th Cir. 2009) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, —, 129 S. Ct. 1937, 1949 (2009)) (alteration in *Sinaltrainal*). "Stated differently, the factual allegations in a complaint must 'possess enough heft' to set forth 'a plausible entitlement to relief'

. . . ." *Fin. Sec. Assurance, Inc. v. Stephens, Inc.*, 500 F.3d 1276, 1282 (11th Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557, 559, 127 S. Ct. 1955, 1966-67 (2007)).

A.

The difficulty at the heart of this case is in deciding how to resolve the tension between the pro-exclusivity tenets of patent law and the pro-competition tenets of antitrust law. That difficulty is made less difficult, however, by the law's pro-precedent tenets. Our earlier decisions carry us much of the way to a resolution in this case.

This Court first confronted an antitrust challenge to a reverse payment settlement in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003). The facts of that case parallel the facts of this one: Two generic manufacturers alleged that the patent for a drug listed in the Orange Book was invalid, the patent holder filed infringement claims against the generic manufacturers, and the parties settled before a court decided the merits of the claims. *Id.* at 1298-300. One generic manufacturer received millions of dollars in exchange for acknowledging the validity of the pioneer's patent and agreeing not to enter the market until another generic manufacturer did or until the patent expired, whichever came first. *Id.* at 1300. The other generic manufacturer, also in exchange for millions of dollars, agreed not to enter the market until one of those two events occurred or until a court held that the patent was invalid, whichever came first. *Id.*

Several private parties filed an antitrust lawsuit against the three manufacturers alleging that the settlement agreements were per se illegal contracts in restraint of trade in violation of Section 1 of the Sherman Act.[5] *See id.* at 1295-96; *see also* 15 U.S.C. § 1 ("Every contract . . . in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal."). The district court agreed with the plaintiffs and granted their motion for partial summary judgment. *See Valley Drug*, 344 F.3d at 1295, 1301. After the court granted the drug companies' request for permission to take an interlocutory appeal, *see* 28 U.S.C. § 1292(b), we reversed. *Valley Drug*, 344 F.3d at 1295, 1313.

Our *Valley Drug* decision began by acknowledging that antitrust laws typically prohibit agreements where one company pays a potential competitor not to enter the market, but we reasoned that reverse payment settlements of patent litigation presented atypical cases because "one of the parties own[s] a patent." *Id.* at 1304. The patent made all the difference because it meant that the patent holder had a "lawful right to exclude others" from the market. *Id.*; *see also* 35 U.S.C. § 154(a)(1) ("Every patent shall

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[5] The analysis of whether a reverse payment agreement gives rise to antitrust liability is the same for claims brought under the Sherman Antitrust Act, which was involved in *Valley Drug*, and under the Federal Trade Commission Act, which is involved in this case. *See Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (applying the same antitrust analysis to Sherman Act and FTC Act claims).

. . . grant to the patentee . . . the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States . . . ."); *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215, 100 S. Ct. 2601, 2623 (1980) ("[T]he essence of a patent grant is the right to exclude others from profiting by the patented invention."). The district court, we explained, "failed to consider" those exclusionary rights in its antitrust analysis when it held that the agreements were per se illegal. *Valley Drug*, 344 F.3d at 1306. Because one party to the reverse payment agreements held a patent, the agreements did not necessarily decrease the level of competition in the market. *Id.* at 1309. It followed that the district court had erred in using a per se test for determining the legality of the agreements. *See id.* ("If [the patent holder] had a lawful right to exclude competitors, it is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit."); *see also Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1065-66 (11th Cir. 2005) ("By their nature, patents create an environment of exclusion, and consequently, cripple competition. The anticompetitive effect is already present."); *cf. Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J., sitting by designation) ("In a reverse-payment case, the settlement leaves the competitive situation unchanged from before the [generic manufacturer] tried to enter the market.").

After deciding to reverse the district court's partial grant of summary judgment in favor of the plaintiffs in *Valley Drug*, we went on to discuss several other matters "that promise[d] to be relevant on remand." *Valley Drug*, 344 F.3d at 1306. We first addressed the plaintiffs' argument that the analysis on remand should disregard the patent altogether because after the parties had entered into their settlement agreements a federal district court had invalidated the patent at issue. According to the plaintiffs in *Valley Drug*, that post-settlement invalidation meant the patent holder "never had any patent rights," which meant the settlements necessarily excluded more competition from the market than the patent holder was lawfully entitled to exclude (namely, none). *Id.* at 1306-07. Which meant, according to the plaintiffs, there were no patent rights to shield the settlements from antitrust attack, which meant the settlements were "subject to *per se* condemnation." *Id.* at 1306.

We rejected that argument, explaining that a court must judge the antitrust implications of a reverse payment settlement as of the time that the settlement was executed. *Id.* "[T]he mere subsequent invalidity of the patent does not render the patent irrelevant to the appropriate antitrust analysis." *Id.* at 1306-07. For that reason, even though the patent at issue in *Valley Drug* was in fact invalid, its terms had to be given full effect. *See id.* at 1305 (explaining that, at the time of settlement, the patent holder had "the right to exclude others from making, using, or selling

anhydrous terazosin hydrochloride until October of 2014, when [the patent] is due to expire").

Our decision to give full effect to the patent's terms in *Valley Drug* means that even a court judgment about a patent's *actual* exclusionary power, unless that judgment comes before settlement, does not count. What does count is the patent's "*potential* exclusionary power" as it appeared at the time of settlement. *Id.* at 1311 (emphasis added). The patent in *Valley Drug* had the potential to exclude competition at the time of settlement because, at that time, "no court had declared [the] patent invalid." *Id.* at 1306; *cf.* 35 U.S.C. § 282 ("A patent shall be presumed valid."). Because the patent had that potential at the time of settlement, we treated the holder as though it had an exclusionary right at that time. *See Valley Drug*, 344 F.3d at 1306.

Our discussion in *Valley Drug* about the "potential exclusionary power" of patents did not mean, however, that all reverse payment settlements of patent litigation are immune from antitrust attack. A patent holder and any of its challengers cannot enter into an agreement that excludes more competition than the patent has the potential to exclude. If a reverse payment settlement reduces generic competition to a greater extent than the patent grant potentially does, the holder of the patent has used the settlement to buy exclusionary rights that are not contained in the patent grant, and those additional rights are vulnerable to antitrust attack. *See id.* at 1312 ("[T]he patent exception to antitrust liability . . . is limited by the

terms of the patent and the statutory rights granted the patentee."); *cf. United States v. Masonite Corp.*, 316 U.S. 265, 277, 62 S. Ct. 1070, 1077 (1942) ("The owner of a patent cannot extend his statutory grant by contract or agreement. A patent affords no immunity for a monopoly not fairly or plainly within the grant."). Put another way, a patent gives its holder a "bundle of rights," *CMS Indus., Inc. v. L.P.S. Int'l, Ltd.*, 643 F.2d 289, 294 (5th Cir. 1981),[6] but any new exclusionary rights the holder buys to add to that bundle do not fall within the scope of the patent grant and for that reason do not fall within the scope of the patent's antitrust immunity.

In keeping with those principles, we said in *Valley Drug* that parties to a reverse payment settlement are immune from antitrust liability if the anticompetitive effects of their settlement fall "within the scope of the exclusionary potential of the patent." 344 F.3d at 1311. If any provisions of the settlement create restraints on competition beyond that scope, however, those excesses "may then be subject to traditional antitrust analysis to assess their probable anticompetitive effects in order to determine whether [they] violate § 1 of the Sherman Act."[7] *Id.* at 1312. What

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[6] In *Bonner v. City of Prichard*, 661 F.2d 1206, 1209 (11th Cir. 1981) (en banc), we adopted as binding precedent all decisions of the former Fifth Circuit handed down before October 1, 1981. The *CMS* decision was issued on April 22, 1981.

[7] The traditional antitrust analysis consists of two tests: the "per se" test and the "rule of reason" test. *See Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1064 (11th Cir. 2005). Under the per

was left for the district court to do on remand was to consider "the scope of the exclusionary potential of the patent [and] the extent to which the[] provisions of the Agreements exceed that scope." *Id.*

B.

Our next decision involving an antitrust challenge to a reverse payment settlement of patent litigation came in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005). Schering, which held the patent for a drug called K-Dur 20, settled lawsuits it had filed against two generic drug manufacturers, Upsher-Smith Laboratories, Inc. and ESI Lederle, Inc. *Id.* at 1058-60. Schering's settlement with Upsher had two main parts: (1) Upsher agreed not to enter the K-Dur 20 market until five years before Schering's patent expired, and (2) Schering paid Upsher more than $60 million to license some of Upsher's other drug products. *Id.* at 1059-60. Schering's settlement with the other generic manufacturer, ESI, also had two main parts: (1) ESI agreed not to enter the K-Dur 20 market until almost three years before Schering's patent expired; and (2) Schering paid ESI $5 million in legal fees and $15 million to license some of ESI's oth-

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se test, the challenged restraint categorically violates the antitrust laws because it is "so obviously anticompetitive, or so unlikely to be pro-competitive, that [it] can be deemed to violate [the antitrust laws] without much more than an examination of the agreement itself and the relationships of the parties to the agreement." *Valley Drug*, 344 F.3d at 1303. Under the rule of reason test, the legality of the challenged restraint hinges upon whether it promotes or suppresses competition. *See Schering-Plough*, 402 F.3d at 1064.

er drug products, plus another $10 million if ESI's generic drug received FDA approval. *Id.* at 1060-61 & n.8.

The FTC determined in an administrative proceeding that the settlement agreements violated the FTC Act and the Sherman Act. *Id.* at 1058. Although it did not expressly say that reverse payment agreements are per se illegal, the FTC's order nonetheless announced a rule prohibiting all reverse payment settlements in which the generic company receives anything of value in exchange for deferring its research, development, or entry to market. *Id.* at 1062. The defendant drug companies petitioned this Court to review the order, we did so, and we vacated it. *Id.* at 1076.

We began our review of the FTC's order by reiterating what we had said in *Valley Drug*: neither the rule of reason nor the per se test is an appropriate way to analyze the antitrust implications of a reverse payment settlement of patent litigation. *Id.* at 1065. That traditional analysis is inappropriate because one of the signatories to the settlement holds a patent, and a patent conveys the right to "cripple competition." *Id.* at 1066. The proper analysis, we explained, "requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects." *Id.* (citing *Valley Drug*, 344 F.3d at 1312). The essence of this three-prong analysis is an evaluation of whether the settlement agreements contain provisions that restrict competi-

tion beyond the scope of the exclusionary potential of the patent. Cf. United States v. Singer Mfg. Co., 374 U.S. 174, 196-97, 83 S. Ct. 1773, 1785 (1963) ("[I]t is . . . well settled that the possession of a valid patent or patents does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly."); In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 213 (2d Cir. 2006) ("[T]here is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.").

After describing that analysis in *Schering-Plough*, we defined the potential exclusionary scope of the K-Dur 20 patent, giving full force to the exclusionary rights it potentially conveyed. Under the patent, Schering could exclude both of the generic companies from the K-Dur 20 market. *Schering-Plough*, 402 F.3d at 1066. The patent also gave Schering the "right to grant licenses, if it so chooses." *Id.* at 1067. Those exclusionary and licensing rights existed until the patent expired on September 5, 2006, or until the generic manufacturers "proved either that the . . . patent was invalid or that their products . . . did not infringe Schering's patent." *Id.* at 1066-67.

With the potential exclusionary scope of the patent defined in *Schering-Plough*, we then evaluated whether the settlements extended Schering's exclusionary rights beyond that scope. That was simple to do. The settlement with Upsher permitted that company to market its generic K-Dur 20 product more than five years before the expiration of Schering's patent, and

the settlement with ESI allowed it to market its generic product almost three years before the patent expired. *Id.* at 1068-71. The settlements excluded competition for a shorter period of time (five years less and three years less) than the face of the patent allowed. For that reason, we held that the reverse payment settlements did not impermissibly extend Schering's patent monopoly.

Our *Schering-Plough* decision also rejected the FTC's argument that Schering had agreed to pay too much money to settle the case and that the generic companies had agreed to stay off the market for too long. *See id.* at 1073. If that were true, the FTC asserted, it meant that Schering must have paid the generic companies not only to settle the infringement lawsuit but also to obtain increased exclusionary rights in the K-Dur 20 market. *See id.* In other words, the FTC claimed that Schering used the reverse payment settlements not just to protect its legitimate bundle of patent rights, but also to mask a "naked payment" to horizontal competitors in order to expand the scope of its monopoly. *Id.* at 1070, 1072.

We rejected the FTC's contention in part because it did not take into account the underlying patent litigation, which was "certain[ ] to be a bitter and prolonged process." *Id.* at 1072; *see also id.* at 1075 ("[T]he size of the payment . . . should not dictate the availability of a settlement remedy."). We emphasized that "[t]he general policy of the law is to favor the settlement of litigation," *id.* at 1072, and reiterated that patent litigation is costly and complex, *see id.* at

1073-74. All three drug companies in *Schering-Plough* were facing high risks and costs if they continued to litigate the infringement action. *See id.* at 1075 (discussing the costs of attorney fees, expert fees, and discovery expenses, and noting the "caustic environment of patent litigation" that may increase the "period of uncertainty" for patenting and marketing new drugs). The agreements among the parties reflected that high-stakes reality, so their settlements "fell well within the protections of the [K-Dur 20] patent, and were therefore not illegal." *Id.* at 1076.[8]

C.

Our third and most recent decision involving the antitrust implications of reverse payment settlements is *Andrx Pharmaceuticals, Inc. v. Elan Corp.*, 421 F.3d 1227 (11th Cir. 2005). The district court in that case granted a patent holder's motion for judgment on

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[8] The FTC's brief in this case places great weight on our statement in *Schering-Plough* that a proper antitrust analysis of reverse payment agreements needs to "evaluate the *strength of the patent*." 402 F.3d at 1076 (emphasis added). The FTC argues that evaluating the "strength of the patent" means evaluating "the strength of the patent holder's claims of validity and infringement, as objectively viewed at the time of settlement." We disagree. When read in the context of the facts and the reasoning of *Schering-Plough*, the phrase "strength of the patent" refers to the potential exclusionary scope of the patent—that is, the exclusionary rights appearing on the patent's face and not the underlying merits of the infringement claim. Nowhere in the *Schering-Plough* opinion did we actually evaluate the merits of the infringement claim when defining how much competition the patent could potentially exclude from the market.

the pleadings, but we reversed the judgment because the plaintiff had sufficiently pleaded an antitrust claim. It had done so in two ways. First, the complaint in *Andrx* alleged that the generic manufacturer had agreed "to refrain from *ever* marketing a generic" version of the patented drug. *Id.* at 1235 (emphasis added). If true, that meant the settlement agreement blocked generic competition *after* the patent expired, and in that way excluded competition beyond "the scope of exclusion intended by the . . . patent." *Id.*

The other way the complaint in *Andrx* stated a plausible antitrust claim was by alleging that the settlement agreement allowed the generic company to retain its 180-day exclusivity period of 21 U.S.C. § 355(j)(5)(B)(iv) even though that company had "no intention of marketing its generic drug." *Andrx*, 421 F.3d at 1231. If true, that meant the 180-day period, which begins to run "after the date of first commercial marketing," 21 U.S.C. § 355(j)(5)(B)(iv)(I), would never be "trigger[ed]," *Andrx*, 421 F.3d at 1231. As a result, the exclusivity period would have acted like a cork in a bottle, blocking *other* generic competition from pouring into the market.[9] By doing that, the settlement created anti-

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[9] In 2003 Congress amended the statutory provisions governing the 180-day exclusivity period to keep corks out of bottles by providing that the first paragraph IV ANDA filer forfeits its right of exclusivity if it fails to market a generic drug within certain time periods. *See* 21 U.S.C. § 355(j)(5)(D). A grandfather provision of that amendment specified that the changes would not apply to

competitive effects beyond the scope of the patent. *Id.* at 1235; *see also id.* at 1231 ("[T]he settlement agreement had the effect of preventing *any* generic competition in the . . . market and constituted a conspiracy to restrain trade." (emphasis added)). For those reasons, we held that the complaint in *Andrx* stated a plausible antitrust claim. *Id.* at 1236.

IV.

Our *Valley Drug*, *Schering-Plough*, and *Andrx* decisions establish the rule that, absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.[10] The issue in

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paragraph IV ANDAs filed before the date of enactment. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-713, § 1102(b)(1), 117 Stat. 2066. *See generally Carnco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1284 n.2 (Fed. Cir. 2008) (discussing the amendment).

[10] There was no allegation in our first two decisions that the patents were fraudulently obtained or that the litigation giving rise to the settlement was a sham. *See Valley Drug*, 344 F.3d at 1307-09 & nn.19, 21; *Schering-Plough*, 402 F.3d at 1068. The plaintiff in our third decision did contend that there had been sham litigation, but we rejected that contention as unfounded. *See Andrx*, 421 F.3d at 1233-34.

We stated in *Valley Drug* that: "[A]ppellees have neither alleged nor asserted that the patent was procured by fraud, that appellants knew the patent was invalid, that there was no objective basis to believe that the patent was valid, or any such similar allegations. We therefore are not called upon to decide what the antitrust consequences of such circumstances might be." 344 F.3d at

this case is whether, under that test, the FTC's complaint states an antitrust claim by alleging that Solvay was "not likely to prevail" in the underlying infringement action against Watson, Par, and Paddock.

The FTC argues that its "not likely to prevail" allegation sufficiently states an antitrust claim because a patent has *no* exclusionary potential if its holder was not likely to win the underlying infringement suit. And if the patent has no exclusionary potential, the FTC continues, then any reverse payment settlement that excludes any competition from the market necessarily exceeds the potential exclusionary scope of the patent and must be seen as the patent holder's illegal "'buying off' of a serious threat to competition." Consistent with that reasoning, the FTC urges us to adopt "a rule that an exclusion payment is unlawful if, viewing the situation objectively as of the time of the settlement, it is more likely than not that the patent would not have blocked generic entry earlier than the agreed-upon entry date." Under that rule, the FTC's allegation that Solvay was "not likely to prevail" in the patent litigation would state a plausible antitrust claim.

1307 n.19. We make the same observations about this case and limit our decision in the same way. Although the FTC's complaint alleges that Solvay was "not likely to prevail" in its infringement actions against Watson and Par/Paddock, it does not contend that any of the three companies knew that the patent was invalid or not infringed or that there was no objective basis to believe the patent was valid and infringed. Accordingly, we do not rule out the possibility that sufficient allegations of any of those facts would state a valid antitrust claim.

We decline the FTC's invitation and reject its argument. The FTC's position equates a likely result (failure of an infringement claim) with an actual result, but it is simply not true that an infringement claim that is "likely" to fail actually will fail. "Likely" means more likely than not, and that includes a 51% chance of a result one way against a 49% chance of a result the other way. *Cf. United States v. Frazier*, 387 F.3d 1244, 1280-81 (11th Cir. 2004) ("[I]t is more likely than not—that is, there is more than a fifty-percent chance—that [the event] would have occurred."). Giving the word its plain meaning, as many as 49 out of 100 times that an infringement claim is "likely" to fail it actually will succeed and keep the competitor out of the market. Our decisions focus on the potential exclusionary effect of the patent, not the likely exclusionary effect. *See, e.g., Valley Drug*, 344 F.3d at 1305; *Schering-Plough*, 402 F.3d at 1066; *Andrx*, 421 F.3d at 1235.

In few cases that are settled is the probability needle pointing straight up. One side or the other almost always has a better chance of prevailing, but a chance is only a chance, not a certainty. Rational parties settle to cap the cost of litigation and to avoid the chance of losing. Those motives exist not only for the side that is likely to lose but also for the side that is likely, but only likely, to win. A party likely to win might not want to play the odds for the same reason that one likely to survive a game of Russian roulette might not want to take a turn. With four chambers of a seven-chamber revolver unloaded, a party pulling the trigger

is likely (57% to 43%) to survive, but the undertaking is still one that can lead to undertaking.

Patent litigation can also be a high stakes, spin-the-chambers, all or nothing undertaking. *See Valley Drug*, 344 F.3d at 1308; *Schering-Plough*, 402 F.3d at 1075-76. For the company with a patented drug, it obviously makes sense to settle the infringement action if it is "not likely to prevail," even though that company may have a substantial (up to 49%) chance of winning. On the other side of the settlement equation is the generic drug company that is only "likely to prevail" in the action; with a substantial (up to 49%) chance of losing, that company also has a legitimate motive for settling. When both sides of a dispute have a substantial chance of winning and losing, especially when their chances may be 49% to 51%, it is reasonable for them to settle. That companies with conflicting claims settle drug patent litigation in these circumstances is not a violation of the antitrust laws.

The FTC argues in its brief that "Solvay's patent was vulnerable," that it "knew that its patent was in trouble," and that "its claims of infringement were very much in doubt." Those arguments not only go beyond the allegations of the complaint, which is all that we can consider in this appeal from a Rule 12(b)(6) dismissal, but they also do little more than reflect the reality of patent litigation and the risks it presents to the patent holder. That reality and those risks are precisely why a party is likely to choose to settle a patent dispute even if it might well prevail. When hundreds of millions of dollars of lost profits are at stake,

"even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement." *Valley Drug*, 344 F.3d at 1310; *cf. In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 208 (E.D.N.Y. 2003) ("No matter how valid a patent is—no matter how often it has been upheld in other litigation or successfully reexamined—it is still a gamble to place a technology case in the hands of a lay judge or jury. Even the confident patent owner knows that the chances of prevailing in patent litigation rarely exceed seventy percent. Thus, there are risks involved even in that rare case with great prospects." (alterations and quotation marks omitted)).

There are other reasons to reject the FTC's approach. It would require an after-the-fact calculation of how "likely" a patent holder was to succeed in a settled lawsuit if it had not been settled. Predicting the future is precarious at best; retroactively predicting from a past perspective a future that never occurred is even more perilous. And it is too perilous an enterprise to serve as a basis for antitrust liability and treble damages. *See Valley Drug*, 344 F.3d at 1308 ("Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent."); *cf. Whitmore v. Arkansas*, 495 U.S. 149, 159-60, 110 S. Ct. 1717, 1725 (1990) ("It is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case.").

The FTC's retrospective predict-the-likely-outcome-that-never-came approach would also impose heavy burdens on the parties and courts. It would require, in the FTC's words, "viewing the situation objectively as of the time of the settlement." In this case, assaying the infringement claim "as of the time of settlement" would have required mining through mountains of evidence—when the lawsuit settled, more than 40 depositions had been taken and one side alone had produced more than 350,000 pages of documents. The settlement made that unnecessary, but the FTC's approach would put that burden back on the parties and the court, undo much of the benefit of settling patent litigation, and discourage settlements. Our legal system can ill afford that. *See Schering-Plough*, 402 F.3d at 1075 ("There is no question that settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation."); *see also Valley Drug*, 344 F.3d at 1309 (noting "the important role played by settlement in the enforcement of patent rights"); *cf. In re Tamoxifen Citrate*, 466 F.3d at 202 ("Where a case is complex and expensive, and resolution of the case will benefit the public, the public has a strong interest in settlement." (quotation marks omitted)); *Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1368 (Fed. Cir. 2001) (noting "the important policy of enforcing settlement agreements").

There is also the fact that retrospective prediction, at least in this type of case, is unlikely to be reliable. The FTC itself has recognized as much in the past. In its order in the *Schering-Plough* case, the full

Commission explained that:

> An after-the-fact inquiry by the Commission into the merits of the underlying litigation is not only unlikely to be particularly helpful, but also likely to be unreliable. As a general matter, tribunals decide patent issues in the context of a true adversary proceeding, and their opinions are informed by the arguments of opposing counsel. Once a case settles, however, the interests of the formerly contending parties are aligned. A generic competitor that has agreed to delay its entry no longer has an incentive to attack vigorously the validity of the patent in issue or a claim of infringement.

In re Schering-Plough Corp., No. 9297, 2003 WL 22989651, at *22 (F.T.C. Dec. 8, 2003), *vacated by Schering-Plough*, 402 F.3d 1056. For those reasons, the FTC concluded that "it would not be necessary, practical, or particularly useful . . . to embark on an inquiry into the merits of the underlying patent dispute when resolving antitrust issues in patent settlements." *Id.* at *23. The FTC was right then for the same reasons it is wrong now.

There is another reason to reject the FTC's new approach. Congress has given the United States Court of Appeals for the Federal Circuit exclusive appellate jurisdiction over patent cases. *See* 28 U.S.C. § 1295(a)(1); *see also Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 89, 113 S. Ct. 1967, 1971 (1993); *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 807, 108 S. Ct. 2166, 2173 (1988). This Court and the other non-specialized circuit courts have no exper-

tise or experience in the area. We are ill-equipped to make a judgment about the merits of a patent infringement claim, which is what we would have to do in order to decide how likely the claim was to prevail if it had been pursued to the end. The FTC's approach is in tension with Congress' decision to have appeals involving patent issues decided by the Federal Circuit.

As we discussed at the beginning of this opinion, the FTC warns that the alternative to its approach of looking back to decide what the likely outcome of settled infringement claims would have been is unacceptable. The alternative, according to the FTC, will allow patent holders and potential competitors "to forgo litigation over patent infringement and split up an ongoing stream of monopoly profits, even in situations in which it is evident that it is more likely than not that the patent would be found invalid or not infringed." The FTC believes that, because drug prices will be higher in the absence of competition, the profits generated by a patent holder's monopoly will typically exceed the aggregated profits that all companies individually would earn through competition. As a result, a potential competitor can make more money by dropping its patent challenge in return for a share of the holder's monopoly profits than it can by continuing to attack an invalid patent and bringing a less expensive version of the drug to market before the patent expires.

The FTC's ominous forecast discounts the reality that there usually are many potential challengers to a patent, at least to drug patents. If the patent actually

is vulnerable, then presumably other generic companies, which are not bound by the first challenger's reverse payment settlement, will attempt to enter the market and make their own challenges to the patent. Blood in the water can lead to a feeding frenzy. Although a patent holder may be able to escape the jaws of competition by sharing monopoly profits with the first one or two generic challengers, those profits will be eaten away as more and more generic companies enter the waters by filing their own paragraph IV certifications attacking the patent. *Cf.* Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. Rev. 11, 25 (2004) ("In a world in which there are numerous firms willing and able to enter the market, an exit payment to one particular infringement defendant need not have significant anticompetitive effects. If there is good reason for believing the patent [is] invalid others will try the same thing.").

In closing, it is worth emphasizing that what the FTC proposes is that we attempt to decide how some other court in some other case at some other time was likely to have resolved some other claim if it had been pursued to judgment. If we did that we would be deciding a patent case within an antitrust case about the settlement of the patent case, a turducken task. Even if we found that prospect palatable, we would be bound to follow the simpler recipe for deciding these cases that is laid out in our existing precedent. As we interpret that precedent, the FTC loses this appeal.

AFFIRMED.

APPENDIX B

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

MDL Docket No. 2084
ALL CASES

1:09-MD-2084-TWT

IN RE: ANDROGEL ANTITRUST LITIGATION (NO. II)

Filed: Feb. 22, 2010

ORDER

This is a Multidistrict Litigation proceeding involving antitrust actions that are consolidated for pretrial proceedings. It is before the Court on the Defendants' Motions to Dismiss the Indirect Purchaser Plaintiffs' Complaints [MDL Doc. 8, 9]; the Defendants' Motions to Dismiss the Second Amended Complaint [MDL Doc. 22, 23, 24, 26 and 28]; and the Defendants' Motions to Dismiss the Private Plaintiffs' Second Amended Complaints [MDL Doc. 25, 27 and 29]. For the reasons set forth below, the Defendants' motions are GRANTED in part and DENIED in part.

I. Background

AndroGel is a prescription gel used to treat male hypogonadism. Male hypogonadism is a medical condition where the body does not produce normal levels of testosterone. Symptoms include depression, fatigue, loss of muscle mass, and decreased libido. Physicians prescribe AndroGel to increase levels of testosterone in their patients. Patients apply the gel directly onto their skin. The testosterone penetrates the skin and gradually enters the bloodstream, providing for a sustained release of testosterone. AndroGel is not the only available method of testosterone replacement therapy. Physicians also prescribe testosterone injections or skin patches. But these other methods have not been as effective or as popular as AndroGel. AndroGel has quickly become the most popular form of testosterone replacement therapy. From 2000 to 2007, sales of AndroGel in the United States were over $1.8 billion.

Besins Healthcare, S.A. developed the pharmaceutical formulation for AndroGel. In August 1995, Besins granted Solvay Pharmaceuticals, Inc., a license to sell AndroGel in the United States. Besins also agreed to produce AndroGel and supply it to Solvay once Solvay received approval to sell the drug. To sell any new drug in the United States, a person must file a New Drug Application (NDA) with the Food and Drug Administration (FDA). 21 U.S.C. § 355(a). The NDA must contain a complete report about the drug, including safety and efficacy studies, the composition of the drug, description of how the drug is produced,

and proposed labeling. 21 U.S.C. § 355(b). In April 1999, Solvay filed a NDA for AndroGel with the FDA. In February 2000, the FDA approved Solvay's NDA, and soon after Solvay began selling AndroGel.

Like most pharmaceutical companies that sell new drugs, Solvay sought legal protection against generic versions of AndroGel. Solvay first sought protection under federal drug laws. In April 1999, when Solvay filed its NDA for AndroGel, Solvay also asked the FDA for new drug product exclusivity. This exclusivity prevents the FDA from approving any other application to sell the same drug until the exclusivity period ends. The FDA will grant five years of exclusivity for any NDA that contains active ingredients never previously approved by the FDA. *See* 21 U.S.C. § 355(c)(3)(F)(ii). The FDA will grant three years of exclusivity for any NDA that contains an active ingredient that has previously been approved by the FDA but still includes new clinical investigations essential to approval of the NDA. *See* 21 U.S.C. § 355(c)(3)(F)(iii). AndroGel fell into the latter category, and so in February 2000, the FDA granted Solvay three years of exclusivity.

Solvay also sought protection under federal patent laws. In August 2000, employees from Solvay and Besins filed a patent application with the Patent and Trademark Office (PTO). The application claimed the gel formulation used in AndroGel. It did not claim testosterone itself or testosterone replacement therapy. In January 2003, the PTO granted the application and issued U.S. Patent No. 6,503,894 ('894 pa-

tent).[1] In June 2003, Solvay requested that the PTO correct certain mistakes that it made in the patent. In December 2003, the PTO granted the request and issued a certificate of correction. *See* 35 U.S.C. § 255. Solvay and Besins jointly own the '894 patent. It expires in August 2020. Within thirty days after the PTO issued the '894 patent, Solvay submitted the '894 patent to the FDA for listing in the Orange Book. The Orange Book is a publication by the FDA containing information about each approved drug. 21 U.S.C. § 355(j)(7)(A). For any NDA, a person must also submit any patent that the person believes would be infringed by a generic drug. 21 U.S.C. § 355(b)(1). This requirement applies even if the PTO issues the patent after the person filed a NDA. 21 U.S.C. § 355(c)(2). The FDA accepted Solvay's submission and listed the '894 patent in the Orange Book.

Other pharmaceutical companies soon developed a generic version of AndroGel. To sell a generic drug, a person may file an Abbreviated New Drug Application (ANDA) with the FDA. 21 U.S.C. § 355(j). The Hatch-Waxman Act created the ANDA procedure. Pub. L. No. 98-417, 98 Stat. 1585 (1984). One goal of the Hatch-Waxman Act was to streamline the process for approving generic drugs. *See id.* As a result, an ANDA does not need to contain a complete report about the drug. It can show that the generic drug

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[1] The Court takes judicial notice of the '894 patent. *See Day v. Taylor*, 400 F.3d 1272, 1276 (11th Cir. 2005) (taking notice of a document that was "(1) central to the plaintiff's claim and (2) undisputed").

is bioequivalent to a previously approved drug and then rely on that drug's NDA. *See* 21 U.S.C. § 355(j)(2)(A)(iv). But if there is a patent that claims the previously approved drug, the ANDA must contain an additional certification. The ANDA must certify that (1) the patent has not been listed in the Orange Book, or (2) the patent has expired, or (3) the patent will expire on a certain date, or (4) the patent is invalid or will not be infringed by the generic drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii). When the ANDA certifies that the patent is invalid or will not be infringed, it is known as a Paragraph IV certification. For any ANDA with a Paragraph IV certification, the applicant must also notify the patent holder of the ANDA. 21 U.S.C. § 355(j)(2)(B).

Once Solvay's new drug product exclusivity expired in February 2003, the FDA was authorized to approve generic versions of AndroGel. In May 2003, two companies each submitted ANDAs with Paragraph IV certifications for generic AndroGel. Watson Pharmaceuticals, Inc. submitted the first ANDA, and Paddock Laboratories, Inc. submitted the second ANDA. Both companies also sent notice of their ANDAs to Solvay and Besins. In July 2003, Paddock reached an agreement with Par Pharmaceuticals, Inc. Par agreed to share any litigation costs with Paddock and to sell Paddock's generic AndroGel. In return, Paddock agreed to share profits with Par.

Solvay responded to the ANDAs by asserting its rights under the '894 patent. In August 2003, Solvay's subsidiary, Unimed Pharmaceuticals, Inc., filed patent

infringement actions against Watson and Paddock in this Court. *See Unimed Pharm., Inc. v. Watson Pharm., Inc.*, No. 1:03-CV-2501-TWT (N.D. Ga. Aug. 21, 2003); *Unimed Pharm., Inc. v. Paddock Labs., Inc.*, No. 1:03-CV-2503-TWT (N.D. Ga. Aug. 21, 2003). Solvay alleged infringement based on the filing of the ANDAs. *See* 35 U.S.C. § 271(e)(2)(A). This is not an ordinary infringement action. It is an "artificial" one based solely on the filing of an ANDA. *See Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). If a patent holder files such infringement action within forty-five days of receiving notice of an ANDA with a Paragraph IV certification, the FDA will stay approval of that ANDA for thirty months. 21 U.S.C. § 355(j)(5)(B)(iii). But if before the thirty month period ends a district court decides that the patent is invalid or not infringed, the FDA may approve the ANDA effective on the date of such judgment. *Id.*; *see In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 192 n.4 (2d Cir. 2006). Because Solvay filed infringement actions against Watson and Paddock within forty-five days of receiving notice, the FDA stayed approval of their ANDAs for thirty months.

For the next few years, Solvay, Watson, and Paddock litigated the infringement actions. The two infringement actions followed a similar schedule. From late 2003 to the middle of 2005, the parties engaged in discovery, scheduling, and other initial litigation matters. By August 2005, the parties had filed motions for claim construction. By December 2005, Watson

and Paddock had filed motions for summary judgment on the validity of the '894 patent. All of the motions were fully briefed and ready for decision. While the motions were pending, Watson and Paddock moved towards entering the market with generic AndroGel. In January 2006, the thirty month stay ended, and the FDA approved Watson's ANDA. The FDA, however, continued to stay approval of Paddock's ANDA. The first person to file an ANDA with a Paragraph IV certification receives generic exclusivity. This exclusivity prevents the FDA from approving any subsequent person's ANDA for the same drug until 180 days after the earlier of (1) the date the first person begins commercial marketing of its generic drug or (2) the date a district court enters judgment that the patent is invalid or not infringed, whichever date is earlier. 21 U.S.C. § 355(j)(5)(B)(iv); *see In re Tamoxifen*, 466 F.3d at 193 n.5. Because Watson was the first to file an ANDA for generic AndroGel, it received generic exclusivity over Paddock. In February 2006, Watson prepared a report predicting that it would sell generic AndroGel by January 2007 and that the price would be 75 percent less than brand name AndroGel. In the same month, Par prepared a report predicting that Watson would sell generic AndroGel as early as March 2006 and that Par and Paddock would follow in September 2006.

Before the Court decided any motions in the infringement actions, and before anyone sold generic AndroGel, Solvay, Watson, and Paddock settled. The parties began settlement negotiations in early 2006,

and on September 13, 2006, Solvay entered into settlements with Watson and Paddock. Under the settlement between Solvay and Watson, Solvay agreed to voluntarily dismiss the infringement action, and Watson agreed not to market generic AndroGel until the earlier of August 31, 2015 or the date another company marketed generic AndroGel. Under the settlement between Solvay and Paddock, Solvay agreed to a consent judgment dismissing the infringement action, and Paddock agreed not to market generic AndroGel until the earliest of August 31, 2015, but only if Watson did not assert its 180-day generic exclusivity period, or the date another company launched generic AndroGel, or February 28, 2016.

On the same day as the settlements, Solvay also entered into business promotion agreements with Watson, Par, and Paddock. Under the agreement between Solvay and Watson, Solvay agreed to share profits of AndroGel with Watson, and Watson agreed to promote AndroGel to urologists. Solvay estimated that its annual payments to Watson would be between $15 and $30 million. Under the agreement between Solvay and Par, Solvay agreed to share profits of AndroGel with Par, and Par agreed to promote AndroGel to primary care physicians. Solvay estimated that its annual payments to Par would be about $6 million. Under the agreement between Solvay and Paddock, Solvay agreed to share profits of AndroGel with Paddock, and Paddock agreed to serve as backup supplier of AndroGel. Solvay estimated that

its annual payments to Paddock would be about $2 million.

The settlements prompted an investigation by the Federal Trade Commission (FTC) for violations of antitrust laws. In 2008, the FTC completed its investigation. In 2009, the FTC and a number of private parties filed these antitrust actions against Solvay, Watson, Par, and Paddock. All of the actions were filed in other federal district courts and then transferred to this Court either by change of venue or by order of the United States Judicial Panel on Multidistrict Litigation. There are three groups of Plaintiffs: the FTC, the Direct Purchasers, and the Indirect Purchasers. All of the Plaintiffs allege that the Defendants violated various federal antitrust laws. *See* Sherman Antitrust Act §§ 1-2, 15 U.S.C. §§ 1-2; Federal Trade Commission Act § 5(a), 15 U.S.C. § 45(a). The Indirect Purchasers also allege that the Defendants violated the common law and antitrust laws of about forty states. All of the Plaintiffs assert antitrust claims based on the settlements. They say that Solvay paid Watson, Par, and Paddock millions of dollars for agreeing not to sell generic AndroGel before August 31, 2015. The Direct Purchasers, but not the other Plaintiffs, also assert antitrust claims based on the Defendants' conduct before the settlements. They say that Solvay filed sham infringement actions against Watson and Paddock; Solvay improperly listed the '894 patent in the Orange Book; all of the Defendants participated in a scheme to monopolize the market for generic AndroGel; and Watson, Par, and Pad-

dock agreed not to compete with each other in the market for generic AndroGel. The Defendants now move to dismiss all of the Plaintiffs' claims for failure to state a claim upon which relief can be granted.

II. Motion to Dismiss Standard

A complaint should be dismissed under Rule 12(b)(6) only where it appears that the facts alleged fail to state a "plausible" claim for relief. *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009); Fed. R. Civ. P. 12(b)(6). A complaint may survive a motion to dismiss for failure to state a claim, however, even if it is "improbable" that a plaintiff would be able to prove those facts; even if the possibility of recovery is extremely "remote and unlikely." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556 (2007) (citations and quotations omitted). In ruling on a motion to dismiss, the court must accept factual allegations as true and construe them in the light most favorable to the plaintiff. *See Quality Foods de Centro America, S.A. v. Latin American Agribusiness Dev. Corp., S.A.*, 711 F.2d 989, 994-95 (11th Cir. 1983). Generally, notice pleading is all that is required for a valid complaint. *See Lombard's, Inc. v. Prince Mfg., Inc.*, 753 F.2d 974, 975 (11th Cir. 1985), *cert. denied*, 474 U.S. 1082 (1986). Under notice pleading, the plaintiff need only give the defendant fair notice of the plaintiff's claim and the grounds upon which it rests. *See Erickson v. Pardus*, 551 U.S. 89, 93 (2007) (*citing Twombly*, 550 U.S. at 555).

III. Discussion

A. Patent Infringement Settlements

All of the Plaintiffs assert antitrust claims based on the settlements. They say that the business promotion agreements were really just a way for Solvay to pay Watson, Par, and Paddock for agreeing not to sell generic AndroGel before August 31, 2015. They say that this was an antitrust violation because, without these "reverse payments," Solvay would have either lost its infringement actions or settled on a date for sale of generic AndroGel earlier than August 31, 2015. In either situation, Watson, Par, and Paddock would have sold generic AndroGel before August 31, 2015, and market competition would have substantially reduced the price of AndroGel.

To state an antitrust claim based on the settlements, the Plaintiffs must allege facts that show the settlements were unreasonable restraints of trade. *See Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1303 (11th Cir. 2003). Ordinarily, courts decide whether a restraint is unreasonable by applying either a rule of reason or per se analysis. *Schering-Plough Corp. v. Federal Trade Comm'n*, 402 F.3d 1056, 1064 (11th Cir. 2005). Generally, when one company agrees to pay a competitor not to compete, the agreement is a per se antitrust violation. *Valley Drug*, 344 F.3d at 1304. But "neither the rule of reason nor the per se analysis is appropriate" when a patent settlement is involved. *Schering-Plough*, 402 F.3d at 1065. This is because the general approaches look at "whether the challenged conduct had an anticompetitive effect on

the market. By their nature, patents create an environment of exclusion, and consequently, cripple competition. The anticompetitive effect is already present." *Id.* at 1065-66. Instead of applying a rule of reason or per se analysis, the Eleventh Circuit has established a separate approach for antitrust actions involving a patent settlement. "[T]he proper analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects." *Id.* at 1066.

The Plaintiffs do not allege that the settlements between the Defendants exceed the scope of the '894 patent. First, the settlements only exclude generic AndroGel from the market. The '894 patent claims the gel formulation used in AndroGel and that gel formulation is "necessary to the manufacture and sale of" generic AndroGel. *See Andrx Pharms., Inc. v. Elan Corp., PLC*, 421 F.3d 1227, 1235 (11th Cir. 2005). The settlements do not exclude any product other than generic AndroGel. *Cf. In re Tamoxifen*, 466 F.3d at 213 (listing cases where the settlement did exclude "unrelated or non-infringed products"). Second, the settlements only exclude generic AndroGel from the market until August 31, 2015. This provides for five years less exclusion than the '894 patent, which does not expire until August 2020. Third, the settlements only prevent Watson, Par, and Paddock from selling generic AndroGel. The Plaintiffs do not allege, for example, any agreement to use Watson's 180-day ge-

neric exclusivity period to prevent other companies from selling generic AndroGel. *See id.* at 200. Indeed, Watson says that it relinquished its exclusivity as part of the settlement. (Mem. of Law in Supp. of Defs.' Mot. to Dismiss the FTC's Second Am. Compl., at 18.)[2]

In response, the FTC and the Private Plaintiffs say that the scope of a patent includes more than just the patent's claims and duration. They say that it also includes the likelihood that a patent holder could assert its claims in court and win. But this argument is inconsistent with the Eleventh Circuit's reasoning in *Valley Drug*. In *Valley Drug*, a brand name manufacturer settled its infringement actions against two generic drug manufacturers. One of the generic manufacturers agreed to a final settlement, while the other only agreed to an interim settlement. Under the interim settlement, the generic manufacturer agreed not to sell its product until it got a final judgment in its favor. The brand name and generic manufacturer continued to litigate the infringement action, and eventually the district court held that the brand name manufacturer's patent was invalid. Later, some purchasers of the brand name drug filed antitrust actions against the brand name manufacturer and the two generic manufacturers. They said that per se analysis should apply because the brand name manu-

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[2] Because the Plaintiffs do not allege that the settlements exceed the '894 patent, the Court does not need to go to the third step and examine "the resulting anticompetitive effect." *See Valley Drug*, 344 F.3d at 1312.

facturer's patent was invalid, and so it never really had any patent rights. The Eleventh Circuit disagreed. It held that "the mere subsequent invalidity of the patent does not render the patent irrelevant to the appropriate antitrust analysis." *Valley Drug*, 344 F.3d at 1306-07. It explained that:

> Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent. This uncertainty, coupled with a treble damages penalty, would tend to discourage settlement of any validity challenges except those that the patentee is certain to win at trial and the infringer certain to lose. By restricting settlement options, which would effectively increase the cost of patent enforcement, the proposed rule would impair the incentives for disclosure and innovation.

Id. at 1308; *see also Schering-Plough*, 402 F.3d at 1075; *In re Tamoxifen*, 466 F.3d at 204; *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1337 (Fed. Cir. 2008). Those same concerns apply equally here. Considering whether Solvay would have won its infringement actions creates the same uncertainty that the court in *Valley Drug* believed would severely limit settlements.[3]

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[3] This does not, however, preclude the Plaintiffs from alleging that Solvay filed sham infringement actions against Watson and Paddock. Those allegations will be addressed later in this Order.

The Plaintiffs also say that it should be presumptively unlawful for companies to settle a patent dispute with reverse payments. But this argument is also inconsistent with the Eleventh Circuit's reasoning in *Valley Drug*. In *Valley Drug*, both settlements included substantial payments from the brand name manufacturer to the generic manufacturers. The plaintiffs said that per se analysis should apply because a patent does not include the right to pay for exclusion. The Eleventh Circuit disagreed. It held that per se analysis does not apply to reverse payments. *Valley Drug*, 344 F.3d at 1309. The court explained that:

> The failure to produce the competing . . . drug, rather than the payment of money, is the exclusionary effect, and litigation is a much more costly mechanism to achieve exclusion, both to the parties and to the public, than is settlement. To hold that an ostensibly reasonable settlement of patent litigation gives rise to per se antitrust liability if it involves any payment by the patentee would obviously chill such settlements, thereby increasing the cost of patent enforcement and decreasing the value of patent protection generally. We are not persuaded that such a per se rule would be an appropriate accommodation of the competing policies of the patent and antitrust laws.

Id. (citation omitted). In *Schering-Plough*, the Eleventh Circuit reiterated its holding in *Valley Drug* and explained that reverse payments should not matter to an analysis of antitrust liability:

> We have said before, and we say it again, that the size of the payment, or the mere presence of a payment, should not dictate the availability of a settlement remedy. Due to the 'asymmetrics of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.' . . . What we must focus on is the extent to which the exclusionary effects of the agreement fall within the scope of the patent's protection.

Schering-Plough, 402 F.3d at 1075-76 (*quoting Valley Drug*, 344 F.3d at 1310); *see also In re Tamoxifen*, 466 F.3d at 206; *In re Ciprofloxacin*, 544 F.3d at 1329. Because the Plaintiffs do not allege that the settlements exceed the scope of the '894 patent, it does not matter if the Defendants settled their patent disputes with reverse payments. The Plaintiffs' reverse payment settlement claims must be dismissed.

B. Sham Litigation

Although it is not entirely clear, it appears that the Eleventh Circuit's Hatch-Waxman cases allow antitrust Plaintiffs to assert a claim of "sham litigation" in the context of reverse payment patent infringement settlements. *See Schering-Plough*, 402 F.3d at 1072. The Direct Purchasers allege that Solvay engaged in sham litigation in filing and prosecuting the patent infringement actions against the generic Defendants. They allege that the generic Defendants conspired to restrain trade by entering into settlements of the sham litigation in exchange for a portion of Solvay's monopoly profits.

Solvay, Par and Paddock assert immunity under the Noerr-Pennington doctrine. The Noerr-Pennington doctrine provides that there is no antitrust liability for petitioning the government for an anticompetitive outcome. *Andrx*, 421 F.3d at 1235. It prevents federal antitrust laws from interfering with the First Amendment right to "petition the Government for a redress of grievances." U.S. Const. amend. I; *see also Professional Real Estate Investors v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 56 (1993). Courts have defined petitioning activity to include lobbying for government legislation and seeking redress through administrative or judicial proceedings. *See Eastern R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 136 (1961); *United Mine Workers v. Pennington*, 381 U.S. 657, 670 (1965); *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972).

It is well established that there is a sham litigation exception to Noerr-Pennington immunity. *See Noerr*, 365 U.S. at 144 (noting that there is no protection for petitioning activity that is "a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor"). In this context, the Eleventh Circuit has said that sham litigation has two elements: "(1) the lawsuit is objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits; and (2) the party bringing the allegedly baseless suit did so with a subjective motivation to interfere directly with the business relationships of a

competitor." *Andrx*, 421 F.3d at 1234 (internal quotation marks and emphasis omitted).

The Direct Purchasers say that Solvay's infringement actions were objectively baseless because generic AndroGel clearly did not infringe the original '894 patent.[4] The '894 patent claims a testosterone gel formulation. The formulation is made up of various ingredients; and the relevant ingredient for purposes of the patent litigation is sodium hydroxide. As originally issued, four of the five independent claims in the '894 patent describe a pharmaceutical composition containing 1% to 5% of sodium hydroxide. *See* '894 patent cls. 1, 9, 10, 18. The fifth independent claim does not describe any amount of sodium hydroxide. *See* '894 patent cl. 31. The Direct Purchasers say that neither brand name AndroGel nor generic AndroGel contains anywhere near 1% sodium hydroxide. Indeed, they say that any skilled chemist would recognize that a gel containing even 1% sodium hydroxide is harmful and would burn a patient's skin. The Direct Purchasers say that AndroGel actually contains a diluted sodium hydroxide solution that is 50 to 250 times less concentrated than the compositions described in the '894 patent. In other words, Solvay made a mistake in drafting the '894 patent. Because of this mis-

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[4] The original '894 patent matters because "[antitrust] analysis should focus on what the litigant knew or reasonably could have known at the time the suits were filed." *In re Wellbutrin SR Antitrust Litig.*, No. Civ.A. 04-5525, 2006 WL 616292, *11 (E.D. Pa. Mar. 9, 2006). At the time Solvay filed its infringement actions, the PTO had not yet issued a certificate of correction.

take, the Direct Purchasers say that generic AndroGel clearly did not infringe the original '894 patent.

Solvay says that the error could be corrected by the Court. A district court can correct a patent error "if (1) the correction is not subject to reasonable debate based on consideration of the claim language and the specification and (2) the prosecution history does not suggest a different interpretation of the claims." *Novo Indus., L.P. v. Micro Molds Corp.*, 350 F.3d 1348, 1354 (Fed. Cir. 2003). These "determinations must be made from the point of view of one skilled in the art." *Ultimax Cement Mfg. Corp. v. CTS Cement Mfg. Corp.*, 587 F.3d 1339, 1353 (Fed. Cir. 2009). Solvay says that the Court would have corrected its drafting mistake. First, Solvay says that there is no dispute that the claims should have referred to diluted sodium hydroxide. Agreeing with the Direct Purchasers, Solvay says that any skilled chemist would recognize that a gel containing even 1% sodium hydroxide is harmful and would burn a patient's skin. It also says that the specification includes a table listing the specific composition for brand name AndroGel. This table correctly lists sodium hydroxide as a diluted solution. *See* '894 patent cl.13 table 5 (listing sodium hydroxide as "0.1 N NaOH at 4.72g per 100g of gel [or 4.72%]"). Second, Solvay says that there is nothing in the prosecution history which suggests that it meant for the gel to contain a harmful amount of sodium hydroxide. Based on these arguments, which were made during the patent litigation, Solvay says that it had "a reasonable belief that there [was] a chance" the

Court would judicially correct Solvay's drafting mistake. *See Professional Real Estate Investors*, 508 U.S. at 63 (internal quotation marks omitted). The Direct Purchasers have alleged facts that may support a sham litigation theory of recovery. Therefore, the motions to dismiss should be denied.

The Direct Purchasers also say that Solvay's infringement actions were objectively baseless because the '894 patent clearly did not meet the written description requirement. The written description requirement provides that:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112. The Direct Purchasers say that there is no written description in the specification to support the ranges of sodium hydroxide described in the claims. Those claims describe a pharmaceutical composition containing 1% to 5% of sodium hydroxide. *See* '894 patent cls. 1, 9, 10, 18. The Direct Purchasers say that nothing in the specification mentions any range of sodium hydroxide. The only mention of sodium hydroxide in the specification is the table listing the composition for brand name AndroGel:

Table 5

Composition of AndroGel®

Substance	Amount (w/w) Per 100 g of Gel
Testosterone	1.0 g
Carbopol 980	0.90 g
Isopropyl myristate	0.50 g
0.1 N NaOH	4.72 g
Ethanol (95% w/w)	72.5 g (corresponding to 67 g of ethanol)
Purified water (qaf)	100 g

'894 patent cl.13 table 5. This table refers to a specific amount of sodium hydroxide—4.72% of diluted sodium hydroxide—and does not refer to any range. *Id.*

The Direct Purchasers' allegations regarding the written description requirement are sufficient to state a plausible antitrust claim. "The written description does not have to describe the invention exactly." *Nelson v. K2 Inc.*, No. C07-1660, 2008 WL 4603409, at *1 (W.D. Wash. Oct. 15, 2008). For claims involving ranges, "[t]he question is whether the disclosure provides adequate direction which reasonably would lead one skilled in the art to the particular item or range claimed as the invention." *Id.*; *see also Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d 989, 1000 (Fed Cir. 2000). This raises questions of fact that cannot be resolved at the pleading stage.

D. Overall Scheme

The Direct Purchasers also assert an antitrust claim that all of the Defendants participated in a scheme to monopolize the market for generic AndroGel. The components of this scheme include improper listing in the Orange Book, filing sham infringement actions, and reverse payment settlements. As discussed above, only the sham litigation claim survives. The Direct Purchasers say that, even so, the Court may still consider their overall scheme claim because it would "be [im]proper to focus on specific individual acts . . . while refusing to consider their overall combined effect." *Anaheim v. Southern Cal. Edison Co.*, 955 F.2d 1373, 1376 (9th Cir. 1992). But, while this principle is true, the Direct Purchasers do not actually identify any improper "combined effect" to the Defendants' actions. They simply repeat their allegations about the individual components and then conclude that the overall combined effect of the Defendants' actions was unlawful. *See id.* ("[I]f all we are shown is a number of perfectly legal acts, it becomes much more difficult to find overall wrongdoing."). Such legal conclusions "are not entitled to the assumption of truth." *Iqbal*, 129 S. Ct. at 1950.

E. Agreements Between Watson, Par, and Paddock

The Direct Purchasers also assert an antitrust claim that Watson, Par, and Paddock agreed not to compete with each other in the market for generic AndroGel. They say that this claim does not involve any patent rights, and so it should be subject to either

a rule of reason or per se antitrust analysis. But the Direct Purchasers did not assert this claim or provide any supporting factual allegations in their complaints. The first time they mentioned an agreement between Watson, Par, and Paddock was in their response brief to the Defendants' motions to dismiss. (Pls.' Mem. of Law in Opp'n of Defs.' Mots. to Dismiss the Second Am. Compl., at 55.) This was too late. "[A] plaintiff cannot amend the complaint by arguments of counsel made in opposition to a motion to dismiss." *Kuhn v. Thompson*, 304 F. Supp. 2d 1313, 1321 (M.D. Ala. 2004). In the post-*Twombly* world, the complaint is judged as it is and not on whether a set of facts could be imagined that would support the claim.

F. State Law Claims

In addition to violating federal antitrust laws, the Indirect Purchasers also allege that the Defendants violated the common law and antitrust laws of about forty states. But the factual allegations for both types of claims are the same. The Indirect Purchasers also do not identify any differences between federal antitrust laws and the relevant state laws. Because the Plaintiffs' allegations do not state a plausible antitrust claim under federal law, the Indirect Purchasers also do not state a plausible antitrust claim under state law. *See In re Tamoxifen*, 466 F.3d at 198 (noting that the district court "dismissed the plaintiffs' state law claims, which had alleged violations of the antitrust laws of seventeen states . . . , because those claims were based on the same allegations as the plaintiffs' federal antitrust claims"); *R.J.*

Reynolds Tobacco Co. v. Phillip Morris, Inc., 199 F. Supp. 2d 362, 396 (M.D.N.C. 2002) ("Because [p]laintiffs do not allege any facts that suggest that [d]efendant's conduct is unlawful beyond the conduct that is the basis for their federal claims, [p]laintiffs' state common law and statutory claims fail as well.").

G. Leave to Amend

The Indirect Purchasers ask for leave to file a consolidated amended complaint. But they made this request in a footnote within their response brief to the Defendants' motions to dismiss. "In the event that the Court grants Defendants any relief requested . . . , we request leave to file a Consolidated Amended Complaint." (End-Payor Pls.' Opp'n to Defs.' Mots. to Dismiss, at 6 n.5.) This is not an appropriate request for leave to amend. The request must be made by motion. *See* Fed. R. Civ. P. 7(b)(1); *Posner v. Essex Ins. Co.*, 178 F.3d 1209, 1222 (11th Cir. 1999) ("Where a request for leave to file an amended complaint simply is imbedded within an opposition memorandum, the issue has not been raised properly."). The request must also either include "the substance of the proposed amendment or attach a copy of the proposed amendment." *Long v. Satz*, 181 F.3d 1275, 1279 (11th Cir. 1999).

IV. Conclusion

For the reasons set forth above, the Defendants' Motions to Dismiss [MDL Doc. 8, 9, 22 and 23] are GRANTED as to the claims of the FTC and the Indirect Purchasers. The Defendants' Motions to Dis-

miss [MDL Doc. 24, 25, 26, 27, 28 and 29] are GRANTED in part and DENIED in part as to the claims of the Direct Purchasers.

SO ORDERED, this 22 day of Feb., 2010.

/s/ THOMAS W. THRASH
THOMAS W. THRASH, JR.
United States District Judge

APPENDIX C

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 10-12729-DD

FEDERAL TRADE COMMISSION,
PLAINTIFF-COUNTER DEFENDANT-APPELLANT

v.

WATSON PHARMACEUTICALS, INC., SOLVAY PHARMACEUTICALS, INC., DEFENDANTS-APPELLEES
PAR PHARMACEUTICAL COMPANIES, INC.,
PADDOCK LABORATORIES, INC.,
DEFENDANTS-COUNTER CLAIMANTS-APPELLEES

[Filed: July 18, 2002]

Appeal From The United States District Court
For The Northern District Of Georgia

ON PETITION(S) FOR REHEARING AND
PETITION(S) FOR REHEARING EN BANC

Before: CARNES, KRAVITCH and FARRIS,* Circuit Judges.

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* Honorable Jerome Farris, United States Circuit Judge for the Ninth Circuit, sitting by designation.

PER CURIAM:

The Petition(s) for Rehearing are DENIED and no Judge in regular active service on the Court having requested that the Court be polled on rehearing en banc (Rule 35, Federal Rules of Appellate Procedure), the Petition(s) for Rehearing En Banc are DENIED.
ENTERED FOR THE COURT:

/s/ ED CARNES
ED CARNES
United States Circuit Judge

ORD-42

APPENDIX D

1. 15 U.S.C. 1 provides in relevant part:

Trusts, etc., in restraint of trade illegal, penalty

Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. * * *

2. 15 U.S.C. 2 provides in relevant part:

Monopolizing trade a felony; penalty

Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, * * * .

3. 15 U.S.C. 45(a)(1)-(2) provides in relevant part:

Unfair methods of competition unlawful; prevention by Commission

(a) Declaration of unlawfulness; power to prohibit u fair practices; inapplicability to foreign trade

(1) Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.

(2) The Commission is hereby empowered and directed to prevent persons, partnerships, or corporations * * * from using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce.

4. 15 U.S.C. 53 provides in relevant part:

False advertisements; injunctions and restraining orders

* * * * *

(b) Temporary restraining orders; preliminary injunctions

Whenever the Commission has reason to believe—

(1) that any person, partnership, or corporation is violating, or is about to violate, any provision of law enforced by the Federal Trade Commission, and

(2) that the enjoining thereof pending the issuance of a complaint by the Commission and until such complaint is dismissed by the Commission or set aside by the court on review, or until the order of the Commission made, there-on has become final, would be in the interest of the public—

the Commission by any of its attorneys designated by it for such purpose may bring suit in a district court of the United States to enjoin any such act or practice. Upon a proper showing that, weighing the equities and considering the Commission's likelihood of ultimate

success, such action would be in the public interest, and after notice to the defendant, a temporary restraining order or a preliminary injunction may be granted without bond: *Provided, however,* That if a complaint is not filed within such period (not exceeding 20 days) as may be specified by the court after issuance of the temporary restraining order or preliminary injunction, the order or injunction shall be dissolved by the court and be of no further force and effect: *Provided further,* That in proper cases the Commission may seek, and after proper proof, the court may issue, a permanent injunction. Any suit may be brought where such person, partnership, or corporation resides or transacts business, or wherever venue is- proper under section 1391 of title 28. In addition, the court may, if the court determines that the interests of justice require that any other person, partnership, or corporation should be a party in such suit, cause such other person, partnership, or corporation to be added as a party without regard to whether venue is otherwise proper in the district in which the suit is brought. In any suit under this section, process may be served on any person, partnership, or corporation wherever it may be found.

* * * * *

5. 21 U.S.C. 355(j) (2006 & Supp. V 2011) provides:

New drugs

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients

of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 321(p) of this title, and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling

approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (B) through (F) of subsection (b)(1) of this section;

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

(i) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) TIMING OF NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

(I) if the certification is in the application, not later than 20 days after. the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(iii) RECIPIENTS OF NOTICE.—An applicant required under this subparagraph to give notice shall give notice to—

(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(II) the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(iv) CONTENTS OF NOTICE.—A notice required under this subparagraph shall—

(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage

form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds-

(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(D)(i) An applicant may not amend or supplement an application to seek approval of a drug referring to a different listed drug from the listed drug identified in the application as submitted to the Secretary.

(ii) With respect to the drug for which an application is submitted, nothing in this subsection prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(iii) Within 60 days after December 8, 2003, the Secretary shall issue guidance defining the term "listed drug" for purposes of this subparagraph.

(3)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except-

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the re-

viewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (O)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).

(4) Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds—

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show—

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 321(p) of this title,

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that

the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(0) or because the drug and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of this section of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section, the Secretary has published a notice of opportunity for hearing to

withdraw approval of the listed drug under subsection (c) of this section for grounds described in the first sentence of subsection (e) of this section, the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (6), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); or

(K) the application contains an untrue statement of material fact.

(5)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) of this section before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed—

(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(iv) 180-DAY EXCLUSIVITY PERIOD.—

(I) EFFECTIVENESS OF APPLICATION.— Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commer-

cial marketing of the listed drug) by any first applicant.

(II) DEFINITIONS.—In this paragraph:

(aa) 180-DAY EXCLUSIVITY PERIOD.—The term "180-day exclusivity period" means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) FIRST APPLICANT.—As used in this subsection, the term "first applicant" means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) SUBSTANTIALLY COMPLETE APPLICATION.—As used in this subsection, the term "substantially complete application" means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) TENTATIVE APPROVAL.—

(AA) IN GENERAL.—The term "tentative approval" means notification to an ap-

plicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or section 355a of this title, or there is a 7-year period of exclusivity for the listed drug under section 360cc of this title.

(BB) LIMITATION.—A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(C) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—

(I) IN GENERAL.—No action may be brought under section 2201 of title 28 by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) FILING OF CIVIL ACTION.—If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its

principal place of business or a regular and established place of business.

(III) OFFER OF CONFIDENTIAL ACCESS TO APPLICATION.—For purposes of subclause (I)(cc),the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no

other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

(I) IN GENERAL.—If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) NO INDEPENDENT CAUSE OF ACTION. Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(D) FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.—

(i) DEFINITION OF FORFEITURE EVENT.—In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:

(I) FAILURE TO MARKET.—The first applicant fails to market the drug by the later of—

(aa) the earlier of the date that is—

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) of this section is withdrawn by the holder of the application approved under subsection (b) of this section.

(II) WITHDRAWAL OF APPLICATION.—The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(III) AMENDMENT OF CERTIFICATION.—The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualify-

ing the applicant for the 180-day exclusivity period.

(IV) FAILURE TO OBTAIN TENTATIVE APPROVAL.—The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) AGREEMENT WITH ANOTHER APPLICANT, THE LISTED DRUG APPLICATION HOLDER, OR A PATENT OWNER.—The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of title 15, except that the term includes section 45 of title 15 to the extent that that section applies to unfair methods of competition).

(VI) EXPIRATION OF ALL PATENTS.—All of the patents as to which the applicant submitted a

certification qualifying it for the 180-day exclusivity period have expired.

(ii) FORFEITURE.—The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(iii) SUBSEQUENT APPLICANT.—If all first applicants forfeit the 180-day exclusivity period under clause (ii)—

(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

(II) no applicant shall be eligible for a 180-day exclusivity period.

(E) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(F)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b) of this section.

(ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance

with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section for such drug.

(iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approv-

al of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) of this section.

(v) If an application (or supplement to an application) submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from September 24, 1984.

(6) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approv-

al of the drug under this subsection shall be withdrawn or suspended—

(A) for the same period as the withdrawal or suspension under subsection (e) of this section or this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(7)(A)(i) Within sixty days of September 24, 1984, the Secretary shall publish and make available to the public—

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) of this section before September 24, 1984;

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsec-

tion (c) of this section or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (b) or (c) of this section respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(B) A drug approved for safety and effectiveness under subsection (c) of this section or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or September 24, 1984, whichever is later.

(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under paragraph (6) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

(i) for the same period as the withdrawal or suspension under subsection (e) of this section or paragraph (6), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secre-

tary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(8) For purposes of this subsection:

(A)(i) The term "bioavailability" means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

(ii) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may assess bioavailability by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of drug action.

(B) A drug shall be considered to be bioequivalent to a listed drug if—

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar ex-

perimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

(C) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.

(9) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of—

(A) the name of the applicant,

(B) the name of the drug covered by the application,

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment.

The information the Secretary is required to maintain under this paragraph with respect to an application

submitted under this subsection shall be made available to the public after the approval of such application.

(10)(A) If the proposed labeling of a drug that is the subject of an application under this subsection differs from the listed drug due to a labeling revision described under clause (i), the drug that is the subject of such application shall, notwithstanding any other provision of this chapter, be eligible for approval and shall not be considered misbranded under section 352 of this title if—

(i) the application is otherwise eligible for approval under this subsection but for expiration of patent, an exclusivity period, or of a delay in approval described in paragraph (5)(B)(iii), and a revision to the labeling of the listed drug has been approved by the Secretary within 60 days of such expiration;

(ii) the labeling revision described under clause (i) does not include a change to the "Warnings" section of the labeling;

(iii) the sponsor of the application under this subsection agrees to submit revised labeling of the drug that is the subject of such application not later than 60 days after the notification of any changes to such labeling required by the Secretary; and

(iv) such application otherwise meets the applicable requirements for approval under this subsection.

(B) If, after a labeling revision described in subparagraph (A)(i), the Secretary determines that the continued presence in interstate commerce of the labeling of the listed drug (as in effect before the revision described in subparagraph (A)(i)) adversely impacts the safe use of the drug, no application under this subsection shall be eligible for approval with such labeling.

6. 21 U.S.C. 355(j) (2000) provides:

New drugs

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i)

has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 321(p) of this title, and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pur-

suant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (B) through (F) of subsection (b)(1) of this section;

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B)(i) An applicant who makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give the notice required by clause (ii) to—

(I) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

(II) the holder of the approved application under subsection (b) of this section for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

(ii) The notice referred to in clause (i) shall state that an application, which contains data from bioavailability or bioequivalence studies, has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of such drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

(iii) If an application is amended to include a certification described in subparagraph (A)(vii)(IV), the notice required by clause (ii) shall be given when the amended application is submitted.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds—

(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(3)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such

agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review

of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).

(4) Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds—

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show—

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 321(p) of this title,

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug

are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of this section of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section, the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) of this section for grounds described in the first sentence of subsection (e) of this section, the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (6), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); or

(K) the application contains an untrue statement of material fact.

(5)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the appli-

cant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined under the following:

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period

as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision,

(II) if before the expiration of such period the court decides that such patent has been infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of Title 35, or

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of such court decision.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of forty-five days from the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of title 28, for a declaratory judgment with respect to the patent. Any action brought under section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(iv) If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been

submitted under this subsection continuing such a certification, the application shall be made effective not earlier than one hundred and eighty days after—

(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or

(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,

whichever is earlier.

(C) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(D)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of

which has been approved in any other application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b) of this section.

(ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) applica-

tion, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section for such drug.

(iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three

years from the date of the approval of the supplement under subsection (b) of this section.

(v) If an application (or supplement to an application) submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from September 24, 1984.

(6) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—

(A) for the same period as the withdrawal or suspension under subsection (e) of this section or this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale

or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(7)(A)(i) Within sixty days of September 24, 1984, the Secretary shall publish and make available to the public—

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) of this section before September 24, 1984;

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) of this section or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (b) or (c) of this section respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(B) A drug approved for safety and effectiveness under subsection (c) of this section or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or September 24, 1984, whichever is later.

(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under paragraph (6) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

(i) for the same period as the withdrawal or suspension under subsection (e) of this section or paragraph (6), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(8) For purposes of this subsection:

(A) The term "bioavailability" means the rate and extent to which the active ingredient or thera-

peutic ingredient is absorbed from a drug and becomes available at the site of drug action.

(B) A drug shall be considered to be bioequivalent to a listed drug if—

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

(9) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of—

(A) the name of the applicant,

(B) the name of the drug covered by the application,

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment.

The information the Secretary is required to maintain under this paragraph with respect to an application submitted under this subsection shall be made available to the public after the approval of such application.

7. 35 U.S.C. 271 provides in relevant part:

Infringement of patent

* * * * *

(e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit—

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, or

(B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151-158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2)—

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product, and

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product.

The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent

brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

* * * * *

OPPOSITION BRIEF

No. 12-416

Supreme Court of the United States

FEDERAL TRADE COMMISSION, PETITIONER

v.

WATSON PHARMACEUTICALS, INC., ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF IN OPPOSITION

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QUESTION PRESENTED

This case is about settlements of patent litigation brought under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585. Flaws in the Hatch-Waxman Act, including those relating to settlements concluded thereunder, prompted Congress to enact remedial amendments in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. No. 108-173, 117 Stat. 2066.

The settlements in this case involve Abbreviated New Drug Applications (ANDAs) governed by the pre-amendment law, and thus are known as "pre-MMA" settlements. The United States twice has advised this Court that the MMA's remedial changes counsel against granting certiorari in cases involving pre-MMA settlements to address antitrust questions concerning reverse payments.

The question presented here is the same as stated by the United States when it opposed the FTC's petition for a writ of certiorari in *Schering-Plough Corp.* v. *FTC*, 402 F.3d 1056 (CA11 2005), cert. denied, 548 U.S. 919 (2006):

> Whether the antitrust laws prohibit a brand name drug patent holder and a prospective generic competitor from settling patent infringement litigation by agreeing that the generic manufacturer will not enter the market before a future date within the term of the patent and that the patent holder will make a substantial payment to the generic manufacturer.

U.S. Br. I, *supra* (No. 05-273) (filed May 17, 2006).

PARTIES TO THE PROCEEDING

Petitioner is the Federal Trade Commission.

Respondents are Watson Pharmaceuticals, Inc. ("Watson"), Solvay Pharmaceuticals, Inc. ("Solvay"), Par Pharmaceutical Companies, Inc. ("Par"), and Paddock Holdings, Inc. (formerly known as Paddock Laboratories, Inc.) ("Paddock").

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, respondents Par and Paddock state as follows:

Par is wholly owned by Sky Growth Holdings Corporation, which has no parent corporation, and no publicly held company owns 10% or more of the stock of Sky Growth Holdings Corporation. (Sky Growth Holdings Corporation is privately held by individual investors and private investment firms affiliated with TPG Capital, L.P. (formerly Texas Pacific Group).)

Paddock has no parent corporation, and no publicly held company owns 10% or more of the stock of Paddock.

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STATEMENT

This case arises under pre-MMA Hatch-Waxman law, not current law. That matters because Congress's remedial MMA amendments have yielded steadily declining rates of reverse-payment settlements over the past five years (to a new recent low in FY 2011). Another indication that the amendments are working is that the government has not challenged any alleged reverse-payment settlement arising under post-amendment law. Although the United States previously advised the Court that the MMA's changes likely would reduce incentives for reverse-payment settlements and, therefore, counseled against granting certiorari in a pre-MMA case, the petition mentions the MMA only once, in a string-citation. Pet.20.

That new reticence may be due to the United States' switched position since the last administration. Compare, *e.g.*, U.S.Br.11, *Schering-Plough* ("[C]ompeting considerations suggest that the mere presence of a reverse payment in the Hatch-Waxman context is not sufficient to establish that the settlement is unlawful."), with Pet.22 ("The correct approach, taken by the Third Circuit, is to treat reverse-payment agreements as presumptively anticompetitive.").

The United States does not explain its reversal, but does concede it: "In those briefs [in 2004, 2006, and 2007], the United States did not endorse the FTC's view that reverse-payment settlements are presumptively anticompetitive." Pet.21 n.6.

The United States' new position is entitled to little, if any, deference. See Transcript of Oral Argument at 44, *Kiobel* v. *Royal Dutch Petroleum*,

No.10-1491 (Oct. 1, 2012) (Roberts, C.J.) ("[W]hatever deference you are entitled to is compromised by the fact that your predecessors took a different position.").

A. Background

Solvay sued Watson and Paddock, separately, for patent infringement in 2003 (pre-MMA). The cases proceeded in the Northern District of Georgia until 2006 when respondents settled separately. The court encouraged respondents to settle. B.I.O.App.2a ("[Solvay and Par/Paddock] consented to judgment through a final settlement, which was encouraged by the Court pursuant to its Local Rules"); Transcript of Proceedings, *Unimed Pharms.* v. *Paddock Labs.*, No.1:03-CV-2503-TWT (N.D.Ga. Feb. 26, 2004) ("This has all the appearances of a long, complicated, expensive, difficult case. Is there anything that I can do to prevent any of that from happening?").

Claim-construction briefs and partial summary judgment motions remained pending at settlement, and the court never made any substantive rulings in the three years of litigation. Complaint ¶90.

Respondents settled under circuit precedent expressly holding that final settlements of non-sham, Hatch-Waxman litigation that do not restrict generic competition beyond the patent's exclusionary grant do not violate the antitrust laws, regardless of reverse payments. *Andrx Pharms.* v. *Elan Corp.*, 421 F.3d 1227, 1235 (CA11 2005); *Schering-Plough*, 402 F.3d at 1065-1066; *Valley Drug* v. *Geneva Pharms.*, 344 F.3d 1294, 1308 (CA11 2003).

After investigating the settlements administratively for two years (taking twenty-one depositions),

the FTC filed this antitrust suit in the Central District of California. That court transferred this suit and follow-on private suits to the Northern District of Georgia:

> [T]he FTC's desire to create a circuit split for strategic reasons bears little weight on the determination of transfer in the interest of justice and convenience of the parties and witnesses.
>
> ****
>
> Although the FTC points out that Judge Thrash did not enter any substantive rulings in the case, to assert that there would be "little to no judicial economy in transfer" goes too far.

FTC v. *Watson Pharms.*, 611 F.Supp.2d 1081, 1087-1088 (C.D.Cal. 2009).

Additional follow-on suits were centralized before Judge Thrash. *In re Androgel Antitrust Litig. (No.II)*, 655 F.Supp.2d 1351 (J.P.M.L. 2009).

The district court dismissed the FTC's complaint relying on the same Eleventh Circuit precedents respondents settled under; the private cases survived dismissal on claims of sham litigation. *Androgel*, 687 F.Supp.2d 1371 (N.D.Ga. 2010); Pet.App.37a-61a.

The FTC did not seek leave to amend, and the court entered final judgment on April 20, 2010. The FTC noticed its appeal on June 10, 2010.[1]

---

[1] Thus, during Justice Kagan's tenure as Solicitor General, the United States may have participated in the FTC's decision whether to appeal.

The court of appeals affirmed on April 25, 2012, relying on the same Eleventh Circuit precedents respondents settled under. *FTC* v. *Watson Pharms.*, 677 F.3d 1298 (CA11 2012); Pet.App.1a-36a. It denied rehearing en banc on July 18, 2012. Pet.App.62a-63a. The FTC did not seek to stay the mandate, which issued on July 27, 2012.

The district court subsequently granted summary judgment in the private cases, holding that neither the patent litigations nor the settlements were a sham. *Androgel*, 2012 WL 5352986, at *7-16. The private plaintiffs have noticed their appeal.

These litigations ensued from the FTC's collateral attack on respondents' settlements. Respondents have been defending those settlements, which undisputedly conform with Eleventh Circuit law, for over six years—twice as long as the patent litigation itself.

B. Regulatory Regime

1. *The Hatch-Waxman Act: balanced goals, flawed implementation.* "The Hatch-Waxman Act establishes procedures designed to facilitate the market entry of lower-priced generic drugs while maintaining incentives to invest in new drug development." U.S.Br.2, *Joblove* v. *Barr Labs.*, 551 U.S. 1144 (2007) (No.06-830) (filed May 23, 2007). That description of Hatch-Waxman's balanced goals appears in each of the United States' prior briefs to the Court. U.S.Br.2, *Schering-Plough*; U.S.Br.2, *Andrx Pharms.* v. *Kroger*, 543 U.S. 939 (2004) (No.03-779) (filed July 9, 2004) (verbatim minus "market").

The petition, however, never mentions Hatch-Waxman's balancing of short-term consumer-welfare

interests in lower-priced drugs with long-term consumer-welfare interests in rewarding research and development. See *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 217 (CA3 2012) ("[I]n passing the Hatch-Waxman Act, Congress drew a careful line between patent protection and the need to provide incentives for competition in the pharmaceutical industry.").

But Hatch-Waxman is all about balance. Generics can provoke patent litigation through a "highly artificial act of infringement," *Eli Lilly* v. *Medtronic*, 496 U.S. 661, 678 (1990), by filing a Paragraph-IV ANDA without risking treble damages. Brand-names, in turn, can obtain a thirty-month stay on generic marketing while litigating the infringement case. To incentivize generics to file Paragraph-IV ANDAs, the first-to-file obtain 180-day exclusivity, which delays other generic entry and maintains higher drug prices.

Petitioner neglects to mention two other important features of Hatch-Waxman. First, the "highly artificial act of infringement" results in asymmetrical risks between brand-name and generic companies:

> Because the generic manufacturer will not have made infringing sales (that would give rise to claims for damages) or incurred production and marketing costs at the time of the infringement suit, its litigation risk will be minimal, whereas the patent holder faces potentially devastating consequences if it loses the litigation. The resulting disparity in the litigants' respective risks may tend to increase the cost of settlement

> for a patent holder and make reverse payments more likely, even when the patent holder's legal claims are relatively strong.

U.S.Br.10, *Joblove*.

Second, before the MMA's remedial changes, settlements between brand-names and generic first-filers could easily bottleneck entry of subsequent filers:

> [T]he 180-day exclusivity period created an incentive for the parties to settle the litigation with a non-entry payment to the generic, under which the generic would delay commercialization of the generic product, thus postponing the commencement of the 180-day exclusivity period and locking other generics out of the market indefinitely.

U.S.Br.11, *Joblove* (internal quotation marks and alterations omitted).

The exclusivity provision, designed to incentivize generics by rewarding first-filers, thus had erected a barrier to entry for subsequent filers.

2. *The MMA's remedial amendments*: "Prompted by concern over the anticompetitive effects of agreements such as those at issue here, Congress amended Hatch-Waxman as part of the 2003 Medicare Amendments." FTC C.A.Br.8, *K-Dur*; see U.S.Br.18, *Andrx* ("[T]he 2003 amendments may reduce the number of agreements containing reverse payments.").

Among other remedial changes, the MMA addressed the bottlenecking of subsequent ANDA filers under Hatch-Waxman's first-filer exclusivity

provisions: "In 2003, Congress provided for forfeiture of the exclusivity period in various circumstances, and also provided that any generic manufacturer that filed an ANDA with a paragraph IV certification on the same day as the first filer would be treated as a first filer itself." U.S.Br.3 n.2, *Joblove*.

Beyond the MMA's new provisions on forfeiture and shared-exclusivity, the FTC recommended five additional remedial changes, and Congress enacted all five.[2]

The petition does not arise under the current landscape for Hatch-Waxman settlements because the settlements here involve ANDAs filed before the MMA became effective. Complaint ¶23. "[T]here are two separate exclusivity frameworks—one for first-filed ANDA applications submitted before December 8, 2003 (pre-MMA) and one for first-filed ANDA applications submitted on or after December 8, 2003 (post-MMA)." *ANDA Litigation: Strategies and Tactics for Pharmaceutical Patent Litigators* 68 (Kenneth L. Dorsney et al. eds., 2012).

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[2] Compare FTC, *Generic Drug Entry Prior to Patent Expiration* i-xi (July 2002), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf, with MMA amendments codified at 21 U.S.C. 355(j)(5)(B)(iii) (limiting brand-name company to one thirty-month stay per ANDA); 355 note (requiring settlements and related agreements to be filed with FTC and DOJ); 355(j)(5)(B)(iv)(I) (adding trigger for first-filer's 180-day exclusivity period for first-filer's marketing of brand-name product, including authorized-generics); 355(j)(5)(B)(iii)(I) (lowering "court decision" trigger for first-filer's exclusivity period to district court decisions); *ibid.* (adding "court decision" trigger for first-filer's exclusivity period for brand-name company's failure to contest a declaratory judgment action).

C. Facts

1. *Under the old Patent Act, Solvay's patent application was not public.* The FDA approved Solvay's New Drug Application (NDA) for AndroGel® in February 2000, and Solvay began sales without patent protection. Complaint ¶¶33-34, 39. Solvay's sales nonetheless were exclusive for three years under FDA regulation—an important fact because it explains (to us now as well as to the watchful generic industry then) why AndroGel® had exclusive, growing sales without patent protection. Complaint ¶34; Pet.App.39a.

Solvay subsequently applied for a patent in August 2000. Complaint ¶39. But that application was confidential under then-existing law; Congress amended the Patent Act three months later to make future applications public. 35 U.S.C. 122(b)(1)(A) (effective Nov. 29, 2000) ("[E]ach application for a patent shall be published ***.").

AndroGel®'s growing sales and apparent lack of patent protection, along with the publicly discernible sunset on its three-year exclusivity, attracted generic attention. Separate from "Paragraph-IV," Hatch-Waxman enables generics to "piggy-back[] on the brand's NDA" by filing an ANDA under Paragraphs-I, -II, or -III, when, respectively, (I) there is no patent on the brand-name's drug, (II) the patent has expired, or (III) the generic company certifies that it will not market its product during the patent's term. *Caraco Pharm. Labs.* v. *Novo Nordisk*, 132 S.Ct. 1670, 1676-1677 (2012) (citing 21 U.S.C. 355(j)(2)(A)(vii)(I)-(III)).

In December 2000, more than two years before Solvay's regulatory exclusivity would expire in February 2003, Paddock undertook to copy AndroGel® "as close as humanly possible," intending to file a Paragraph-I ANDA. *Androgel*, 2012 WL 5352986, at *3.

Paddock's world changed in January 2003 when, one-month before the three-year exclusivity would expire, the PTO issued Solvay's patent. Complaint ¶42; *Androgel*, 2012 WL 5352986, at *3 n.4 ("The Generics did not realize that AndroGel was patent protected because Solvay's patent application was not public."). Paddock stopped its bioequivalence work, later resuming with the fallback hope of becoming the first Paragraph-IV filer. See *Androgel*, 2012 WL 5352986, at *3. Paddock filed its Paragraph-IV in May 2003, not knowing that Watson had filed one days earlier. *Ibid.*; Complaint ¶¶44-45; Pet.App.41a.

Paddock never had been involved in a Paragraph-IV case and had not anticipated one, so it partnered with Par in July 2003 to take charge of the inevitable litigation, and its expense, in exchange for a share of potential generic profits. Complaint ¶¶46, 69; Pet.App.41a.

When Solvay subsequently sued Watson and Paddock in August 2003, the ANDA-filing numbers in the complaints were the first public indication that there were two Paragraph-IV filers, and that Watson was first-filer. Complaint ¶47; *ANDA Litigation*, *supra*, at 138 ("A key driver for nonlitigation alternatives is whether the generic party is a Paragraph IV first-filer, and this may not be known until around the time of the initial pleadings.").

2. *As the second ANDA filer, Par/Paddock were subject to Watson's exclusivity.* Throughout the litigations, Par/Paddock were blocked by Watson's first-filer exclusivity. Complaint ¶45. When the Hatch-Waxman thirty-month stay expired in January 2006, Watson, as first-filer, was free to launch its product, but FDA regulation barred Par/Paddock from marketing until 180-days after Watson. Complaint ¶¶2, 22-23, 52-54. Because Watson never launched, Par/Paddock never could. *Ibid.*

After three years of litigation, Solvay reached settlement terms with Watson, permitting Watson to enter no later than August 31, 2015 (five years before patent expiration). Complaint ¶¶60-67. After concluding its settlement terms with Watson, Solvay separately offered Par/Paddock the same entry terms subject to Watson's exclusivity. Complaint ¶71. Because that was the earliest settlement-entry date possible for a second-filer, Par/Paddock quickly accepted. *Ibid.*

When Par/Paddock settled with Solvay, Watson's 180-day exclusivity still applied. Complaint ¶45. Thus, Par/Paddock could obtain the same entry date as Watson "only if Watson did not assert its 180-day generic exclusivity period." Pet.App.44a. After the parties executed separate, confidential settlement agreements, Watson relinquished its first-filer exclusivity with the FDA, furnishing Par/Paddock an unanticipated windfall: the same entry date as the first-filer. B.I.O.App.4a ¶6.

The FTC alleges that the 2015 entry date had little value:

> *Watson* agreed not to market generic AndroGel until 2015 even though it knew of Solvay's plans to introduce a "line extension" product that would eliminate or substantially reduce potential sales of generic AndroGel by 2015. *** *Solvay told Watson* of its plans for a line extension product during settlement negotiations.

Complaint ¶¶62-63 (emphasis added); see Pet.6.

Conspicuously absent from these allegations is any mention of Par/Paddock, who were in the pre-MMA backseat throughout.

3. *Respondents settled under Eleventh Circuit precedent.* The scope-of-the-patent test was governing law in the Eleventh Circuit when respondents settled: absent allegations of sham-litigation or fraud in obtaining the patent, Hatch-Waxman settlements that do not restrict generic competition beyond the patent's exclusionary grant do not violate the antitrust laws, regardless of reverse payments. See p.2, *supra*.

Petitioner does not allege that: either settlement entails restrictions beyond the patent's exclusionary grant, Solvay's patent was obtained by fraud, or the patent litigations were shams. Complaint ¶¶65, 76, 86. The settlements undisputedly qualify for the safe harbor under which respondents settled.

Contemporaneous with the settlements, Solvay and Watson, and Solvay and Par/Paddock, entered into separate co-marketing agreements for AndroGel®. Complaint ¶¶66, 77. Eleventh Circuit law undisputedly permitted such transactions contemporaneous with Hatch-Waxman settlements. Furthermore, no legal objection to the co-marketing

agreements exists beyond petitioner's objection to the simultaneity with settlement. See generally *Sorrell* v. *IMS Health*, 131 S.Ct. 2653, 2659 (2011) ("Speech in aid of pharmaceutical marketing *** is a form of expression protected by the Free Speech Clause of the First Amendment."). Solvay and Paddock entered a manufacturing agreement, without which Solvay's sole source for AndroGel® was a company in Europe. Complaint ¶¶32, 84.

4. *Solvay and Par/Paddock are bound by the district court's Consent Judgment and Order of Permanent Injunction.* Solvay and Watson ended their litigation with a voluntary stipulation of dismissal. Solvay and Par/Paddock took a different path: asking the court to enter a consent judgment. Complaint ¶¶68, 80. The resulting Consent Judgment and Order of Permanent Injunction (B.I.O.App.1a-6a) is a final judgment with the force of res judicata and currently binds Solvay and Par/Paddock to their compromise terms on generic entry.

5. *After the Eleventh Circuit affirmed dismissal of this case, the Third Circuit decided an unrelated case.* "The key allegation in the FTC's complaint is that [Solvay] was 'not likely to prevail' in infringement actions that it brought against the generic manufacturers and then settled." Pet.App.3a; see Complaint ¶86. The Eleventh Circuit affirmed dismissal relying on its same precedents under which respondents had settled. It held that petitioner's allegation that Solvay was "not likely to prevail" did not state an antitrust claim against settlements undisputedly within the scope-of-the-patent. Pet.App.28a-30a. That decision accorded with the

other circuits that had adjudicated antitrust challenges to final Hatch-Waxman settlements. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (CAFC 2008) (*Cipro*); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (CA2 2006).

Three months later, in an unrelated case, the Third Circuit became the only circuit to reject the scope-of-the-patent test in favor of a presumption that "treat[s] any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade." *K-Dur*, 686 F.3d at 218.

REASONS FOR DENYING THE PETITION

The MMA remedial amendments demarcate the old Hatch-Waxman world from the new. This case falls on the wrong side of that line. Driven by some of the same concerns asserted in the petition, Congress recalibrated Hatch-Waxman's competitive landscape, resulting in sharply declining reverse-payment settlement rates. That this case arises under pre-amendment law is reason alone to deny the petition. *Verizon Commc'ns* v. *Law Offices of Curtis V. Trinko*, 540 U.S. 398, 412 (2004) ("One factor of particular importance is the existence of a regulatory structure designed to deter and remedy anticompetitive harm. Where such a structure exists, the additional benefit to competition provided by antitrust enforcement will tend to be small, and it will be less plausible that the antitrust laws contemplate such additional scrutiny.").

In *Schering-Plough*, the United States opposed the FTC's petition, advising the Court: "The decision below does not conflict with any decisions of this Court ***." U.S.Br.1. *Schering-Plough* is the precedent respondents settled under, and the precedent the Eleventh Circuit followed in upholding their settlements. The United States continued: "[T]he public policy favoring settlements, and the *statutory right of patentees to exclude competition within the scope of their patents*, would potentially be frustrated by a rule of law that subjected patent settlements involving reverse payments to automatic or near-automatic invalidation." U.S.Br.10-11 (emphasis added). Petitioner argues that under this Court's precedents it stated a claim "by alleging the existence and circumstances of a presumptively anticompetitive reverse-payment agreement." Pet.24. There is no principled basis for reconciling these positions. Respondents' reliance and repose interests in settlements concluded in 2006, undisputedly in conformity with Eleventh Circuit law, should not depend on the outcome of an election any more than this Court's antitrust jurisprudence should.

The Eleventh Circuit's decision here is no less correct than *Schering-Plough* despite petitioner's allegation that "[h]ad the patent suit proceeded, Solvay's patent was unlikely to prevent generic entry." Complaint ¶3. This Court has never exposed litigants to antitrust liability on such flimsy allegations. *Prof'l Real Estate Investors* v. *Columbia Pictures Indus.*, 508 U.S. 49, 62 (1993) (denying antitrust claim because "sham litigation must constitute the pursuit of claims so baseless that no reasonable litigant could realistically expect to secure

favorable relief"); *Walker Process Equip.* v. *Food Mach. & Chem.*, 382 U.S. 172, 173 (1965) (holding that "enforcement of a patent obtained by fraud on the Patent Office may be the basis of an action under §2 of the Sherman Act"); *Standard Oil* v. *United States*, 283 U.S. 163, 171 (1931) ("Where there are *legitimately conflicting* [patent] claims or threatened interferences, a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act.") (emphasis added); cf. *Whitmore* v. *Arkansas*, 495 U.S. 149, 159-160 (1990) ("It is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case."), cited in *Watson*, Pet.App.32a.

That the Third Circuit created a conflict only *subsequent* to the Eleventh Circuit's decision here is reason to deny (and not hold) this petition. Petitioner's contention that the Third Circuit's decision "has already led to inconsistent results in separate challenges to the same reverse-payment agreements," Pet.11, refers exclusively to the K-Dur settlements and is demonstrably false even as to those. There has not been (and may never be) any inconsistent result involving the K-Dur settlements: the Eleventh Circuit upheld them against the FTC's challenge based on the evidence taken at trial before the ALJ, Pet.30-31; the Third Circuit reversed summary judgment and remanded for further proceedings, which may offer the private plaintiffs the same trial opportunity the FTC had.

And petitioner can hardly complain of a circuit split that it sought to create: "We are looking to find cases so that we can create, for example, a split in the circuits that would militate toward the Supreme

Court taking a case. I can't discuss any of our individual investigations publicly, but we are looking to find a case." Testimony of Jon Leibowitz, Commissioner, FTC, *The Generic Drug Maze: Speeding Access to Affordable Life-Saving Drugs, Hearing Before Senate Special Committee on Aging*, 109th Cong. 51 (2006) (testifying a few months before FTC began investigating respondents' settlements and ultimately sued in California).

Indeed, petitioner prefers the Third Circuit's rule and plans to litigate there: "If [certiorari is denied], of course, we'll simply be forced to bring pay-for-delay cases in the Third Circuit for years to come." Remarks of FTC Chairman Jon Leibowitz, Sixth Annual Georgetown Law Global Antitrust Enforcement Symposium (Sept. 19, 2012), at 4, http://www.ftc.gov/speeches/leibowitz/120919jdlgeorgetownspeech.pdf. Petitioner's litigation options similarly belie its contention that it will be harmed by "flexible venue provisions" for appeal of Commission administrative decisions. Pet.11; see U.S.Br.19, *Schering-Plough* (disputing same forum-shopping argument by the FTC).

Significantly, the Third Circuit created the circuit split by misapplying one of this Court's abrogated former precedents, which was plain error. The panel also ignored that "while the federal patent laws favor full and free competition in the use of ideas in the public domain over the technical requirements of contract doctrine, settlement of litigation is more strongly favored by the law." *Flex-Foot, Inc.* v. *CRP, Inc.*, 238 F.3d 1362, 1369 (CAFC 2001), cited in *Watson*, Pet.App.33a; *Cipro*, 544 F.3d at 1333-1334;

Tamoxifen, 466 F.3d at 202-203; *Schering-Plough*, 402 F.3d at 1072.

This case is not needed to address the Third Circuit's error subsequent to the decision in this case. Petitioner concedes that the *K-Dur* petitions "would be adequate vehicles for deciding the question presented," Pet.29, and this Court rarely grants certiorari in a civil case due to a later-developing conflict. See pp.26-27 & n.6, *infra*.

I. Reverse-Payment Rates Are Declining After The MMA, And Neither This Case Nor *K-Dur* Arises Under Current Law.

The question presented is confined to Hatch-Waxman settlements. Pet.27 ("Payments from the plaintiff to the defendant are scarcely an essential or traditional feature of settlement practice—to the contrary, they appear to be largely unknown outside the Hatch-Waxman context.").[3] Steadily declining reverse-payment rates over the past five years cabin the issue further. The United States predicted that decline, twice advising the Court that the MMA amendments likely would reduce incentives for reverse-payment settlements and, therefore, coun-

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[3] See U.S.Br.24 n.9, *K-Dur* ("[S]uch payments are essentially unknown in the settlement of other patent litigation."); U.S.Br.10, *Joblove* ("The Hatch-Waxman Act provides particular incentives for reverse payments in the context of settlements of patent infringement claims involving pharmaceutical products."); U.S.Br.10, *Schering-Plough* ("[T]he Hatch-Waxman Act may also create unique justifications for reverse payments ***."); U.S.Br.15-16, *Andrx* ("Settlements with reverse payments *** appear to be rare outside the Hatch-Waxman context.").

seled against granting certiorari in cases arising under pre-MMA law, like this one.

A. Reverse-payment rates have been declining since 2006.

Since the MMA, the FTC issues annual reports on Hatch-Waxman settlements. The latest report indicates that in FY 2011 there were 156 "final settlements," of which 28 (18%) were "potential pay-for-delay" settlements. See *Agreements Filed with FTC under MMA Act of 2003: Overview of Agreements Filed in FY 2011*, at 2, http://www.ftc.gov/os/2011/10/1110mmaagree.pdf.

The FTC defines "potential pay-for-delay" as settlements: (i) providing for anything other than immediate generic entry upon settlement, regardless of how long prior to patent expiration the settlement permits entry; and (ii) conferring any value to the generic apart from the value of early entry. *Ibid.*; see S. 27, 112th Cong. § 3(a)(2) (reported out of Judiciary Committee July 22, 2011) (pending FTC-proposed amendment to FTC Act establishing violation for Hatch-Waxman settlements where the "ANDA filer receives anything of value" and "agrees to limit *** sales of the ANDA product for any period of time"). (To whatever extent the remnants that do not make it out of the sausage factory are meaningful, the current bill prohibiting reverse-payment settlements is preceded by others in prior Congresses that have not become law. See U.S.Br.20 n.9, *Joblove* (citing bills pending in 2007).)

The FTC's latest annual report, *supra*, also indicates that while "potential pay-for-delay" rates

peaked at 50% in FY 2006, they have declined to a recent low in FY 2011.[4]

The declining rates of even "potential" reverse-payment settlements counter the government's contention that they "are increasingly common in the drug industry." Pet.16. Because such settlements occur only under Hatch-Waxman and rates are falling steadily, the question presented appears to be of waning importance after Congress's remedial amendments.

Declining rates during 2006-2011 are particularly significant because that period coincides with the "scope-of-the-patent" test being the unanimous rule among circuits that had adjudicated antitrust challenges to final Hatch-Waxman settlements

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[4] Overview of Final Settlements

(2004-2011)

Fiscal Year	2004	2005	2006	2007	2008	2009	2010	2011
Final Settlements	14	11	28	33	66	68	113	156
Potential Pay-for-Delay	0	3	14	14	16	19	31	28
	0%	27%	50%	42%	24%	28%	27%	18%

From presentation by Bradley S. Albert, Deputy Assistant Director, FTC, *"Are Reverse Payments Dead?"* program sponsored by ABA Section of Antitrust Law, Healthcare and Pharmaceuticals Committee (Nov. 10, 2011).

(CA11, CA2, CAFC). Reverse-payment rates continued falling despite favorable case law.

The industry largely has resolved to forgo reverse payments. Empirically, this natural experiment debunks the government's newly cynical prediction that "[i]f reverse-payment agreements are treated as presumptively lawful, such arrangements will be highly attractive to both brand-name manufacturers and their would-be generic competitors." Pet.19. No doubt, there will be even fewer reverse-payment settlements given the Third Circuit's recent decision.

B. The FTC has not challenged any settlement arising under current law.

The government has litigated only three reverse-payment cases. Those settlements occurred in a discrete era (1997-2006) and involved pre-MMA ANDAs. This enforcement history is another reality check on petitioner's contention that the issue is exceptionally important.

1. *K-Dur® settlements (1997)*: The K-Dur settlements occurred fifteen years ago. The Third Circuit's recent decision concerns private-litigation challenges to those settlements. Separately, the FTC challenged the K-Dur settlements administratively, and after a two-month trial, the ALJ upheld the settlements. The Commission reversed, but the Eleventh Circuit vacated the Commission's decision. The FTC's challenge is over, and the Third Circuit's reversal of summary judgment in the private cases may provide those plaintiffs the same trial opportunity the FTC had.

Significantly, the private plaintiffs survived a motion to dismiss even though the district court

applied the scope-of-the-patent test. *In re K-Dur Antitrust Litig.*, 338 F.Supp.2d 517, 532-533 (D.N.J. 2004).

2. *Provigil® settlements (2005-2006)*: The FTC next litigated against settlements concluded in late 2005 and early 2006. The FTC survived a motion to dismiss even though the district court applied the scope-of-the-patent test. *King Drug of Florence* v. *Cephalon*, 702 F.Supp.2d 514, 528-529 (E.D.Pa. 2010). The FTC and private cases are stayed pending resolution of the *K-Dur* petitions.

3. *AndroGel® settlements (2006)*: The settlements in this case occurred in 2006.

The government has not challenged any alleged reverse-payment settlement occurring since. See *Overview of FTC Antitrust Actions in Pharmaceutical Services and Products* 13-19 (June 2012), http://www.ftc.gov/bc/healthcare/antitrust/rxupdate.pdf.

All three challenges involve Paragraph-IV ANDAs filed *before* the December 8, 2003 effective date of the MMA amendments and, therefore, are governed by pre-MMA law. See Complaint ¶23; Pet.App.27a n.9. Because of the time lag between a generic's Paragraph-IV filing and any subsequent litigation settlement, a settlement occurring after the MMA amendments (in 2006 for example) may still involve a pre-MMA ANDA. That is the case here, but is decreasingly likely for settlements occurring in 2007 and later. This lag explains the decline in reverse-payment rates since 2006. See p.19 & n.4, *supra*. The MMA's remedial changes just took time to affect ensuing settlements.

The MMA amendments are working. Intervention by the Court at this time is unwarranted, particularly in a case arising under pre-amendment law.

C. The United States twice advised the Court not to take cases arising under pre-MMA law.

In 2004, the United States advised the Court in *Cardizem/Andrx* (CA6): "This Court's review also may be unwarranted in light of certain amendments to the Hatch-Waxman Act that were enacted by Congress in 2003 ***." U.S.Br.18, *Andrx*. The pre-MMA origin of this case (and *K-Dur*) is important because declining reverse-payment rates and the fact that the government has not challenged any post-MMA settlements appear to be consequences of those remedial amendments—two of which the United States specifically advised the Court were likely to reduce incentives for reverse-payment settlements.

First, the MMA increases the likelihood that *multiple* ANDA filers will be awarded 180-day exclusivity. See 21 U.S.C. 355(j)(5)(B)(iv)(II)(bb). The United States invoked this shared-exclusivity amendment as counseling against certiorari for a pre-MMA case: "[A]llowing multiple ANDA applicants to obtain the 180-day exclusivity period[] may increase the transaction costs for pioneer drug companies that seek to enter into agreements with those applicants. On balance, therefore, the 2003 amendments may reduce the number of agreements containing reverse payments." U.S.Br.18, *Andrx*.

The Eleventh Circuit echoed that point here (albeit without addressing the MMA amendment) when discussing the infeasibility of a brand-name

company shielding a weak patent by buying off multiple generic challengers:

> If the patent actually is vulnerable, then presumably other generic companies, which are not bound by the first challenger's reverse payment settlement, will attempt to enter the market and make their own challenges to the patent. Blood in the water can lead to a feeding frenzy. Although a patent holder may be able to escape the jaws of competition by sharing monopoly profits with the first one or two generic challengers, those profits will be eaten away as more and more generic companies enter the waters by filing their own paragraph IV certifications attacking the patent.

Pet.App.35a-36a.

Second, the MMA added forfeiture provisions that can deprive a first-filer of 180-day exclusivity. In 2007, the United States advised the Court in *Tamoxifen/Joblove* (CA2):

> Congress amended the Hatch-Waxman Act to provide for forfeiture of the 180-day exclusivity period for various reasons ***. As a practical matter, therefore, it may now be more difficult for a first-filing generic manufacturer to enter into a settlement and then use the 180-day exclusivity period effectively to lock other generic manufacturers out of the market ***.

U.S.Br.19-20, *Joblove*.

Thus, because the MMA amendments significantly impair the ability of settlements under current law to bottleneck other potential generic challengers,

anticompetitive incentives for reverse payments are diminished. See U.S.Br.9-10, *Schering-Plough* (discussing pre-MMA bottlenecking potential and resulting incentives for reverse payments).

As the United States twice advised the Court, Congress's significant remedial changes in the MMA (including those proposed by the FTC, see p.7 & n.2, *supra*) have created a new competitive landscape for Hatch-Waxman litigation and settlements that counsels against granting certiorari in a case arising under pre-amendment law. The merits briefs and any ensuing decision in this case would be strewn with digressions about how things used to be pre-MMA versus how things might maybe would be or probably ought to be in a case arising under current law.

II. This Case Has Other Atypical Facts That Are Unlikely To Recur.

This case not only fails to present the Court with a Hatch-Waxman settlement governed by current law, it also has unusual facts that render it an unsuitable vehicle for the question presented.

A. The generics were unaware of Solvay's pending patent because of a flaw in the Patent Act that Congress subsequently remedied.

This case presents the unusual situation in which generics spent years copying a brand-name drug without attempting to "design around" any patent because, under then-existing law, patent applications were not public. See pp.8-9, *supra*. This anachronistic fact insulates this case from one of petitioner's principal arguments, namely, that Hatch-Waxman settlements harm consumer welfare when

brand-names use reverse payments to settle challenges from generics who themselves have innovated by designing around the brand-name's patent:

> In particular, a generic competitor may be able to design its product to satisfy FDA regulations regarding generic drugs yet avoid infringing a patent ***. Some scholars have concluded that the patent portfolios of brand-name drug manufacturers have grown in recent years with the addition of patents that may be particularly susceptible to being avoided, in whole or in part, by generic competitors.

Pet.17 (citations omitted).

Under current law, a generic makes its Paragraph-IV certification after endeavoring to design around the patent or undertaking to copy the product based on the generic's *a priori* determination that the patent is ripe for an invalidity challenge. Because this case involves a "patent surprise" resulting from a provision of the Patent Act no longer in effect, it is a poor vehicle for addressing the current Hatch-Waxman environment where generics make choices fully informed about pending patents.

B. Respondents settled under circuit precedent expressly permitting reverse payments.

In September 2006, after three years of litigation with no substantive rulings, respondents took the court's advice and executed final settlements. See p.2, *supra*. They relied on Eleventh Circuit precedent holding that a final settlement of patent litigation within the scope of the patent does not violate the antitrust laws, regardless of reverse payments.

See p.2, *supra*. The Eleventh Circuit also had held concerning Hatch-Waxman settlements that the "reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into." *Valley Drug*, 344 F.3d at 1306.

The only reason this petition is arguable under Rule 10 is due to the happenstance that in an unrelated case, the Third Circuit, following the guidance of the government as amici curiae,[5] subsequently diverged from unanimous circuit law and issued an opinion supporting the FTC's favored rule—three months after the Eleventh Circuit's decision in this case and six years after respondents settled.

Further review under these circumstances would deprive respondents of any modicum of repose. The Court rarely grants certiorari in a civil case where a conflict develops only after that case was decided. The Court did so in *Tidewater Oil Co.* v. *United States*, 409 U.S. 151 (1972): "Because this decision raises an important question of federal appellate jurisdiction and because a conflict among the circuits subsequently developed on this question, we granted certiorari." *Id.* at 153 (footnote omitted). But there, the petitioner in the subsequent case that created the conflict did *not* seek review of that question. See Petition for Writ of Certiorari at 2, *Fisons Ltd.* v.

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[5] In addition to amicus briefs from the FTC and United States, a deputy solicitor general argued for forty-seven minutes at the *K-Dur* oral argument, available at http://www.ca3.uscourts.gov/oralargument/ListArgumentsAll.aspx (No.10-2077) (Dec. 12, 2011); see *id.* at 00:32-00:35 (Sloviter, J.) ("Yeah, well you can go, I mean, it's the government we want to hear.").

United States, 405 U.S. 1041 (No.71-971) (filed Jan. 31, 1972). Therefore, the Court had to take the case that was decided before the conflict arose if the Court hoped to address the conflict at all.

Not so here, where this case is unnecessary to address the subsequent conflict created by the Third Circuit. The *K-Dur* petitions (filed before this one) present the issue.[6]

It cannot be right that parties can litigate for three years over a "highly artificial act of infringement," *Eli Lilly*, 496 U.S. at 678, with no substantive rulings, then, with the court's encouragement, settle their litigations under circuit law expressly holding that settlements within the scope-of-the-patent are legal regardless of reverse payments, and endure the FTC's six-year collateral attack on the settlements—yielding a decision and mandate from the court of appeals upholding the settlements under the same precedent on which the parties relied when they settled—only to find themselves whipsawed into extraordinary review because of a subsequently conflicting decision from another circuit in an unrelated case.

Even if petitioner were to prevail on the merits, there would be no closure but potentially years more litigation over whether, factually, there was even a

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[6] Research yielded only three examples since *Tidewater* where the Court granted certiorari in a civil case to resolve a later-developing conflict. See *Merrill Lynch, Pierce, Fenner & Smith* v. *Curran*, 456 U.S. 353, 356 (1982); *United States* v. *Consumer Life Ins.*, 430 U.S. 725, 727 (1977); *United States* v. *ITT Cont'l Baking*, 420 U.S. 223, 225 (1975).

reverse payment in this case. (*K-Dur*, however, presents an undisputed reverse payment. Pet.30-31.)

Respondents' reliance and repose interests, which are absent in *K-Dur* because petitioners there are the settling parties, warrant prompt denial of this petition even if the Court were to grant the *K-Dur* petitions. For the same reasons, holding this petition would be unjust.

C. The district court imposes the alleged restraint on Par/Paddock's generic entry.

Respondents' private settlement agreements (between Solvay and Watson on one hand, and Solvay and Par/Paddock on the other) could not of their own force end the patent litigations. Instead, Solvay and Watson dismissed their litigation "without prejudice" by filing a stipulation of dismissal "without a court order." Fed.R.Civ.P.41(a)(1)(A)(ii).

Solvay and Par/Paddock took the road less-traveled. They asked the court to enter the Consent Judgment and Order of Permanent Injunction, and the court did so. That order: (i) terminated Solvay and Par/Paddock's litigation "with prejudice"; (ii) enjoins Par/Paddock from selling its generic version of AndroGel® until 2015 at the latest; (iii) guarantees Par/Paddock's right to practice the patent after that date; and (iv) retains continuing jurisdiction to enforce these terms. B.I.O.App.4a-5a ¶¶6, 9-11, 13.

The order binds Solvay and Par/Paddock to their generic-entry compromise and achieves finality and repose (or, at least it was supposed to) in ways that a settlement agreement alone could not. See *United States* v. *Swift*, 286 U.S. 106, 115 (1932) ("We reject

the argument *** that a decree entered upon consent is to be treated as a contract and not as a judicial act."); *SEC* v. *Randolph*, 736 F.2d 525, 528 (CA9 1984) ("A consent decree offers more security to the parties than a settlement agreement where the only penalty for failure to abide by the agreement is another suit."), quoted in *EEOC* v. *Product Fabricators*, 666 F.3d 1170, 1173 (CA8 2012); see also *Schering-Plough*, 402 F.3d at 1072 ("Veritably, the Commission's opinion would leave settlements, including those endorsed and facilitated by a federal court, with little confidence.").

Because Solvay and Par/Paddock successfully *petitioned* the court for an order governing their compromise generic-entry terms, they are immune from antitrust liability under *Noerr-Pennington*:

> We conclude that it would be destructive of rights of association and of petition to hold that groups with common interests may not, without violating the antitrust laws, use the channels and procedures of state and federal agencies *and courts* to advocate their causes and points of view respecting *resolution of their business and economic interests* vis-à-vis *their competitors*.

Cal. Motor Transp. v. *Trucking Unlimited*, 404 U.S. 508, 510-511 (1972) (emphasis added); see *Andrx Pharms.*, 421 F.3d at 1234 (CA11 2005) ("[A]s the Supreme Court has noted, engaging in litigation to seek an anticompetitive outcome from a court is First Amendment activity that is immune from antitrust liability."); *Columbia Pictures Indus.* v. *Prof'l Real Estate Investors*, 944 F.2d 1525, 1528 (CA9 1991) ("A decision to accept or reject an offer of settlement is

conduct incidental to the prosecution of the suit and not a separate and distinct activity which might form the basis for antitrust liability."), aff'd, 508 U.S. 49 (1993); cf. *Valley Drug*, 344 F.3d at 1309 ("The failure to produce the competing [generic] drug, rather than the payment of money, is the exclusionary effect ***.").

Noerr-Pennington immunity trumps the question presented as to the settlement between Solvay and Par/Paddock because petitioner seeks to undo the order that Solvay and Par/Paddock successfully petitioned the court to enter as a continuing injunction enforcing their compromise terms on Par/Paddock's generic entry.

D. As the second ANDA filer, Par/Paddock could not have obtained an earlier settlement-entry date.

Petitioner's theory is that but-for alleged reverse payments, each generic would have obtained an earlier entry date. Complaint ¶¶93-94; Pet.22-23. That theory is inapplicable to second-filer Par/Paddock, whose settlement enabled entry on the *same day* as Watson, 180-days earlier than Watson's pre-MMA exclusivity period otherwise would have permitted. Pet.App.12a. Par/Paddock's settlement is pro-competitive.

Even under petitioner's theory that a settlement enabling generic entry before patent expiration may nonetheless cause anticompetitive "delay," there could only be a purported delay if the second-filer were to enter more than 180-days *after* the first-filer. In the three reverse-payment cases litigated by the FTC (all involving pre-MMA ANDAs), Par/Paddock is

the only second-filer that obtained the same entry date as the first-filer.[7]

Given that Par/Paddock could not have obtained an earlier settlement-entry date than the first-filer, petitioner is left to allege: "If Solvay had settled with Watson only, Par had ample financial incentive to continue to challenge Solvay's patent." Complaint ¶95. Petitioner's theory thus morphs from one alleging a hypothetical, earlier settlement-entry date into one alleging a duty on second-filer Par/Paddock to have continued litigating based on an allegation of "ample financial incentive."

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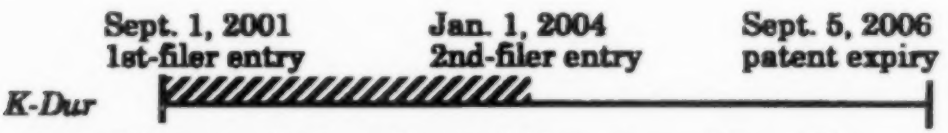
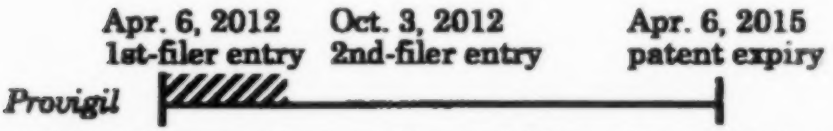
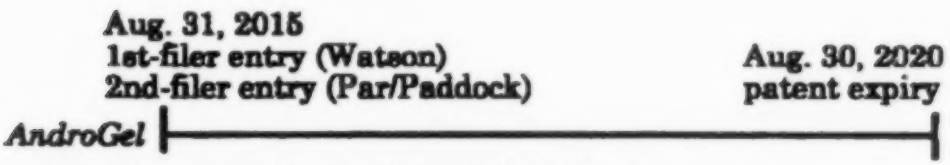
[7]



"Delay" between first- and second-filer entry = 28 months



"Delay" between first- and second-filer entry = 180 days



"Delay" between first- and second-filer entry = zero

From FTC complaints susceptible of judicial notice. See *Tellabs v. Makor Issues & Rights*, 551 U.S. 308, 322 (2007).

But under pre-MMA rules for subsequent ANDA filers, success in a continued litigation by Par/Paddock would have required winning "a final decision of a court from which no appeal *** has been or can be taken." 21 U.S.C. 355 note (explaining pre-MMA rule). And, pre-MMA, *Watson* would have reaped the reward—with Par/Paddock having to wait dutifully to enter 180-days later.

Petitioner's complaint against Par/Paddock dangles by an allegation of "ample financial incentive" for continued litigation (after Watson settled) when Congress changed the statutory scheme precisely because such incentives were lacking. See *Mova Pharm.* v. *Shalala*, 140 F.3d 1060, 1073 (CADC 1998) ("One difficulty is that the 180-day exclusivity period will seemingly always go to the *first* applicant, no matter whose suit satisfies the court-decision trigger ***. It seems odd to reward the first applicant if some later applicant was the party that actually prevailed in the patent-infringement litigation.").

As a Hatch-Waxman practice manual observes:

> If the generic is not a first-filer, it will obtain no exclusivity even if the patent is held invalid or not infringed. Thus, there is little to gain by remaining a party to the litigation and continuing to pay litigation costs and endure discovery burdens. Nonlitigation alternatives should, therefore, be considered all the more seriously to avoid unnecessary litigation costs.

ANDA Litigation, *supra*, at 138.

Rather than presenting a suitable opportunity to address the question presented, petitioner's case as to

the Par/Paddock settlement is bound-up in the old problems with first- versus subsequent-filer settlements addressed by the MMA.

III. The Third Circuit Misapplied *Katzinger*, Which This Court Abrogated In *Lear*.

A. In rejecting the unanimous decisions of three circuits, the Third Circuit purported that its "practical analysis is supported by a long line of Supreme Court cases recognizing that valid patents are a limited exception to a general rule of the free exploitation of ideas." *K-Dur*, 686 F.3d at 215. But the only decision of this Court that the Third Circuit addressed beyond mere citation is *Edward Katzinger Co.* v. *Chicago Metallic Mfg.*, 329 U.S. 394 (1947), abrogated by *Lear, Inc.* v. *Adkins*, 395 U.S. 653 (1969), overruling in part *Automatic Radio Mfg.* v. *Hazeltine Research*, 339 U.S. 827 (1950). Tellingly, neither petitioner nor any of the courts adjudicating antitrust challenges to Hatch-Waxman settlements cites *Katzinger*.

Laboring under this Court's now-overruled patent-licensee estoppel rule, *Katzinger* concerned whether a commercial licensee of a patent could be estopped, by virtue of the licensing agreement, from challenging the validity of the patent. 329 U.S. at 395. *Katzinger* held that because the licensing agreement contained a price-fixing clause for product sold under the license, the licensee was not estopped from challenging patent validity. *Id.* at 399-401. On the same day, the Court decided *MacGregor* v. *Westinghouse Elec. & Mfg.*, 329 U.S. 402, 407 (1947) (likewise holding that in a suit for royalties, a patent licensee can assert invalidity where the commercial-

licensing agreement contains a price-fixing provision). *Katzinger* and *MacGregor* extended the then-existing "anti-trust exception" to the now-overruled patent-licensee estoppel rule. *Lear*, 395 U.S. at 666 ("Five years later [after *Sola Elec.* v. *Jefferson Elec.*, 317 U.S. 173 (1942)], the 'anti-trust exception' was given an even more extensive scope in the *Katzinger* and *MacGregor* cases.").

Sola, *Katzinger*, and *MacGregor* became dead-letter exceptions when this Court finally overruled the patent-licensee estoppel rule itself in *Lear*. *Id.* at 671 ("We are satisfied that [*Automatic Radio* v. *Hazeltine*], itself the product of a clouded history, should no longer be regarded as sound law with respect to its 'estoppel' holding, and that holding is now overruled."). To recap, the law now is that a commercial-licensing agreement *cannot estop* a patent licensee from challenging patent validity, regardless of whether the licensing agreement includes a price-fixing clause.

When *Lear* overruled the estoppel rule, the Court abrogated the patchwork of exceptions to that rule that had accreted over the years in cases like *Sola*, *Katzinger*, and *MacGregor*. That was *Lear*'s point: "During this period, each time a patentee sought to rely upon his estoppel privilege before this Court, the majority created a new exception to permit judicial scrutiny into the validity of the Patent Office's grant." *Id.* at 664. *Lear* continued: "The result has been a failure. *** [T]here has been a chaos of conflicting case law, proceeding on inconsistent premises." *Id.* at 668.

Lear could not have been plainer that it was giving a decent public burial to the former exceptions to the estoppel rule along with the rule itself.

The Third Circuit's decision never mentions any of this, nevermind that *Katzinger*'s holding no longer has any meaning in the law. It simply plucks convenient language from *Katzinger* and moves on. *K-Dur*, 686 F.3d at 216. The Third Circuit concludes its reliance on *Katzinger* with a further leap: "This logic is persuasive with respect to the situation at bar because reverse payments permit the sharing of monopoly rents between would-be competitors without any assurance that the underlying patent is valid." *Ibid.*

But *Katzinger* concerned ordinary patent-licensing agreements. It had nothing to do with settling patent litigation. Even post-*Lear*, a patent-litigation settlement *can estop* a settling alleged infringer from challenging the patent:

> *Lear*, however, did not involve a settlement of litigation, but only the right of a patent licensee to challenge the validity of the licensed patent. The enforcement of settlement of litigation involves another public policy totally absent in *Lear*: the encouragement of settlement of litigation and the need to enforce such settlements in order to encourage the parties to enter into them.

Hemstreet v. *Spiegel, Inc.*, 851 F.2d 348, 350 (CAFC 1988) (holding that settling alleged infringer was estopped from challenging patent and obligated to continue paying royalties under the settlement license even though a third party subsequently invalidated the patent).

Because of these overriding interests in achieving finality and repose in litigation settlements, every circuit that has addressed the issue post-*Lear* agrees that patent-litigation settlement agreements (as opposed to ordinary patent-licensing agreements) can estop settling alleged infringers from challenging the patent.[8]

Thus, the Third Circuit not only misrelied on *Katzinger*'s abrogated "anti-trust exception" to the now-overruled estoppel rule, the court misapplied that orphaned exception to the patent-litigation settlement context. If settling alleged infringers can

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[8] *E.g.*, *Flex-Foot*, 238 F.3d at 1368-1369 ("The license agreement in *Lear* was not created as part of a litigation settlement. *** *Hemstreet* was premised on the policy that while the federal patent laws favor full and free competition in the use of ideas in the public domain over the technical requirements of contract doctrine, settlement of litigation is more strongly favored by the law."); *Wallace Clark & Co.* v. *Acheson Indus.*, 532 F.2d 846, 849 (CA2 1976); *Interdynamics* v. *Firma Wolf*, 653 F.2d 93, 97-98 (CA3 1981); *Schlegel Mfg.* v. *USM Corp.*, 525 F.2d 775, 781 (CA6 1975) (per curiam); *Am. Equip.* v. *Wikomi Mfg.*, 630 F.2d 544, 546-549 (CA7 1980); *United States ex rel. Shell Oil* v. *Barco Corp.*, 430 F.2d 998, 1001-1002 (CA8 1970); see also *Rates Tech.* v. *Speakeasy*, 685 F.3d 163, 167 (CA2 2012) (holding that licensee was not estopped from challenging patent because the "no-challenge clause in this case *** was entered into prior to any litigation between the parties"), petition for cert. filed, 81 U.S.L.W. 3199 (Sept. 28, 2012) (No.12-402) (seeking review of whether patent-settlement estoppel can apply to pre-suit agreements); *Massillon-Cleveland-Akron Sign Co.* v. *Golden State Adver.*, 444 F.2d 425, 425-426 (CA9 1971) (holding that licensee was not estopped from challenging patent where the "covenant[] to refrain from directly or indirectly contesting or questioning the validity of the patent" did not settle patent litigation).

be estopped from challenging a patent post-*Lear*, *Katzinger* has nothing to add.

In creating the circuit split, the panel was untroubled that none of the circuits adhering to the scope-of-the-patent test had cited *Katzinger*. Indeed, the panel patted itself on the back for finding the answer key that no other court had. *K-Dur*, 686 F.3d at 216 ("It appears that these aspects of the Supreme Court's general patent jurisprudence had been overlooked by the Special Master and others adopting the scope of the patent test.").

But beyond the panel's discussion of *Katzinger*, its reliance on this Court's "general patent jurisprudence" consists merely of a string-citation piling on additional convenient language without analyzing whether those cases' holdings support the panel's conclusion that antitrust law regulates settlements of non-sham patent litigation that do not exclude competition beyond the patent's exclusionary grant. See *id.* at 215-216. Not surprisingly, none of the four cases cited remotely supports that conclusion.[9]

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[9] See *Cardinal Chem.*, 508 U.S. at 96, 102 (reversing the Federal Circuit's rule that it lacked jurisdiction to address patent validity "after affirming [a] finding of noninfringement," reasoning that "[t]he Federal Circuit's practice denies the patentee such appellate review"); *Bonito Boats*, 489 U.S. at 161 (holding that federal patent law preempts conflicting state law that mimics patent rights: "[A]llowing the states to create patent-like rights in various products in public circulation would lead to administrative problems of no small dimension."); *Masonite*, 316 U.S. at 280 (holding that price-fixing agreements exceeded the patent's exclusionary grant: "In this case, the price regulation was based on mutual agreement among distributors of competing products, some of whom had competing patents, as we have noted. None of these patents ***

B. The Third Circuit ignored most of this Court's precedents on which the Eleventh, Second, and Federal Circuits had relied in adopting the scope-of-the-patent test. The panel's decision contains nary a citation to:

1. *Standard Oil*, 283 U.S. at 171, discussed in *Schering-Plough*, 402 F.3d at 1072 ("That the parties to a patent dispute may exchange consideration to settle their litigation has been endorsed by the Supreme Court."); *Tamoxifen*, 466 F.3d at 202; *Cipro*, 544 F.3d at 1333.

2. *Walker Process*, 382 U.S. at 177, discussed in *Valley Drug*, 344 F.3d at 1307 ("The only time the Supreme Court has addressed the circumstances under which the patent immunity from antitrust liability can be pierced, it held that the antitrust claimant must prove that the patentee enforced a patent with the knowledge that the patent was procured by fraud on the Patent Office."); *Cipro*, 544 F.3d at 1336; cited in *Watson*, Pet.App.4a.

3. *United States* v. *Singer Mfg.*, 374 U.S. 174, 196-197 (1963) ("'[T]he possession of a valid patent or patents does not give the patentee any exemption from the provisions of the Sherman Act *beyond the limits of the patent monopoly.*'") (emphasis added) (quoting *United States* v. *Line Material*, 333 U.S. 287, 308 (1948)), cited in *Watson*, Pet.App.24a; *Schering-*

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had been held to conflict with or infringe the Masonite patents."); *Pope*, 144 U.S. at 224 (120-year-old case concerning the estoppel rule overruled by *Lear*); *see also Studiengesellschaft*, 670 F.2d at 1135 ("None of the anti-competitive effects of the challenged restriction found by the district court exceed the anticompetitive effects which the patent authorized.").

Plough, 402 F.3d at 1067; *Tamoxifen*, 466 F.3d at 202; see *Valley Drug*, 344 F.3d at 1307 (quoting *Line Material*, 333 U.S. at 309).

4. *Dawson Chem.* v. *Rohm & Haas*, 448 U.S. 176, 215 (1980) ("[T]he essence of a patent grant is the right to exclude others from profiting by the patented invention."), discussed in *Watson*, Pet.App.18a; *Schering-Plough*, 402 F.3d at 1066; *Tamoxifen*, 466 F.3d at 201-202; *Cipro*, 544 F.3d at 1333; *Valley Drug*, 344 F.3d at 1304.

C. The Third Circuit's decision is a solitary outlier, the first ever to diverge from the scope-of-the-patent test. The Third Circuit initially said that "five other circuits have addressed the question," but subsequently conceded that decisions from the Sixth and D.C. Circuits (both concerning the same 1997 interim-litigation agreement) "did not involve a settlement resolving patent litigation." *K-Dur*, 686 F.3d at 209-210; see Pet.13 (conceding that "the Sixth and D.C. Circuits have not adopted specific standards to determine the legality of reverse-payment agreements").

As the United States previously advised the Court: "[*Cardizem/Andrx*] involves the relatively rare situation in which the parties entered into an *interim* agreement that did not resolve the parties' underlying patent dispute. *** The distinction is important because the calculus of competitive costs and benefits is substantially different for interim settlements and final settlements." U.S.Br.7, 17, *Andrx*.

The Sixth and D.C. Circuits are not involved in the conflict single-handedly created by the Third

Circuit's misapplication of *Katzinger*. The panel's plain error—subsequent to the Eleventh Circuit's decision in this thoroughly litigated case—is not a basis for further review here.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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NOVEMBER 2012

APPENDIX

APPENDIX

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF GEORGIA ATLANTA DIVISION

No. 1:03-CV-2503

UNIMED PHARMACEUTICALS, INC., A DELAWARE CORPORATION, AND LABORATORIES BESINS ISCOVESCO, A DELAWARE CORPORATION, PLAINTIFFS,

v.

PADDOCK LABORATORIES, INC. A MINNESOTA CORPORATION, DEFENDANT

[Filed: September 15, 2006]

CONSENT JUDGMENT AND ORDER OF PERMANENT INJUNCTION

This action for patent infringement (the "Litigation") has been brought by Plaintiff Unimed Pharmaceuticals, Inc. ("Unimed") (a wholly-owned subsidiary of Solvay Pharmaceuticals, Inc. ("Solvay")), and Laboratories Besins Iscovesco ("Besins"), against Defendant Paddock Laboratories, Inc. ("Paddock") for infringement of United States Patent No. 6,503,894 (the "'894 Patent"), covering a pharmaceutical transdermal gel sold under the trademark Androgel® (the "Unimed Product"). Each

of Unimed, Solvay, and Besins (the "Plaintiffs") and Paddock, together with its assignee Par Pharmaceutical Companies, Inc. ("Par"), acknowledge there is significant risk to each of them associated with the continued prosecution of this Litigation and have consented to judgment through a final settlement, which was encouraged by the Court pursuant to its Local Rules, and as reflected in the consent judgment set forth herein.

Plaintiffs and Paddock, together with Par, have agreed to enter into a good faith final settlement agreement regarding this Litigation on the expectation and belief that this would result in a number of public interest benefits. Pursuant to a settlement agreement and ancillary patent license agreement (the "Agreements") entered into for the final resolution of this Litigation, Par will be able to market the Paddock Product, as defined herein, by no later than 2016, allowing entry of a generic version of the Unimed Product in advance of the 2020 expiration of the '894 Patent, which competition otherwise might not have occurred or been allowed to continue had Plaintiff prevailed on any one of the numerous claims brought against Paddock in the Litigation.

The proposed settlement also would eliminate the substantial litigation costs that would otherwise be incurred by both Plaintiffs and Paddock during the Litigation, while also serving the public interest by saving judicial resources and avoiding the risks to each of the parties associated with infringement. This will afford Plaintiffs and Paddock the opportunity to more productively use money and other resources that would have been spent in the

continued prosecution and defense of this Litigation, to the benefit of the Parties and consumers alike, such as by investing more money in marketing, research and development and education of physicians and patients regarding use and benefits of the Unimed Product, that will facilitate competition and the benefits therefrom approximately five years earlier than could be achieved if the Paddock Product were permanently enjoined during the life of the '894 patent.

In order to effectuate this settlement, Par consents to the jurisdiction of this Court.

Plaintiffs and Paddock now consent to this Judgment and Order of Permanent Injunction (the "Judgment") and

IT IS HEREBY ORDERED, ADJUDGED AND DECREED:

1. This Court has jurisdiction over the parties and subject matter of this action.

2. The '894 Patent is owned by Plaintiffs (or its affiliates) and is valid and enforceable, as asserted in their Complaint against Paddock, in all respects.

3. Paddock and Par acknowledge that the claims of the '894 Patent are valid and enforceable in all respects.

4. Paddock and Par acknowledge that the sale of the product described in its Abbreviated New Drug Application No. 76-744 (the "Paddock Product") would infringe the claims of the '894 Patent, as asserted in the Complaint against Paddock.

5. Paddock assigned its rights in the Paddock Product to Par and Par has assumed certain obligations to defend Paddock in the Litigation.

6. As a result, Paddock and Par are barred from practicing the '894 Patent until

> the earliest of (a) August 31, 2015, provided there is no commercialization sufficient to trigger Hatch-Waxman 180 day exclusivity; (b) the date any Generic Testosterone Gel Product (as defined in the relevant Agreements) is offered for sale in the Territory (as defined in the relevant Agreements); or (c) in any other event, February 28, 2016, by manufacturing, marketing or selling the Paddock Product, pursuant to the terms of the parties' Agreements that permit the practice of the '894 Patent.

7. The submission of Paddock's Abbreviated New Drug Application No. 76-744 under Section 505(j) of the Federal Food, Drug and Cosmetic Act is an act of infringement of the '894 Patent under 35 U.S.C. 271(e)(2)(A).

8. Paddock and Par would infringe the '894 Patent by selling, offering to sell, importing and/or using the Paddock Product.

9. All affirmative defenses, claims and counterclaims, which have been or could have been raised by Paddock in this action with respect to the validity or enforceability of the '894 Patent, are dismissed with prejudice.

10. Except as agreed to by the parties pursuant to the Agreements in settlement of this Litigation or otherwise, Paddock and Par are also hereby enjoined

and estopped during the term of the '894 Patent, from making any challenge to the validity or enforceability of the '894 Patent with respect to the claims asserted against Paddock, or from marketing and selling the Paddock Product.

11. The foregoing injunction against Paddock and Par shall take effect immediately upon entry of this Judgment, and shall continue generally with respect to the '894 Patent coterminous with the license grant provided by the Agreements, unless earlier terminated or modified by further order of this Court.

12. The parties waive all right to appeal from this Judgment.

13. This Court shall retain jurisdiction of this action and over the parties for purposes of enforcement of the provisions of this Judgment.

14. Each party is to bear its own costs and attorney's fees.

Dated: September 14, 2006

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SO ORDERED, this 15th day of September, 2006

/s/Thomas W. Thrash
Thomas W. Thrash Jr.
United States District Judge

REPLY BRIEF

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No. 12-416

In the Supreme Court of the United States

FEDERAL TRADE COMMISSION, PETITIONER

v.

WATSON PHARMACEUTICALS, INC., ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

REPLY BRIEF FOR THE PETITIONER

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In the Supreme Court of the United States

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FEDERAL TRADE COMMISSION, PETITIONER

v.

WATSON PHARMACEUTICALS, INC., ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

REPLY BRIEF FOR THE PETITIONER

As the government's certiorari petition explains, the question presented in this case implicates an untenable circuit conflict on a well-defined legal issue of exceptional importance to the national economy. The need for this Court's review is reinforced by the pending petitions in *Merck & Co.* v. *Louisiana Wholesale Drug Co.*, No. 12-245 (filed Aug. 24, 2012), and *Upsher-Smith Laboratories Inc.* v. *Louisiana Wholesale Drug Co.*, No. 12-265 (filed Aug. 29, 2012) (collectively, the *K-Dur* petitions). The petitioners in those cases are pharmaceutical companies that disagree with the government's position on the merits but agree that a square circuit conflict exists and that the question presented requires nationwide resolution.

Two of the respondents in this case (Watson Pharmaceuticals, Inc. and Solvay Pharmaceuticals, Inc.)—who are the only parties to one of the reverse-payment

agreements that the Federal Trade Commission (FTC) challenges here—agree that the FTC's petition should be granted. Respondents Par Pharmaceutical Cos. and Paddock Holdings, Inc. (collectively, Par) oppose further review and contend that the Court should deny the FTC's petition outright even if it grants the *K-Dur* petitions on the same question presented. Par identifies no sound basis for denying review here.

A. Par Offers No Substantial Reason To Deny All The Certiorari Petitions

The *K-Dur* respondents suggest that this Court may benefit from "await[ing] a final judgment and a complete record in a reverse payment case." Br. in Opp. at 10, *K-Dur*, *supra* (No. 12-245). The FTC's petition seeks review of a final judgment affirming the dismissal of the FTC's complaint. The FTC's allegations in this case reflect its extensive investigation of the AndroGel® reverse-payment agreements; they are not the sort of half-informed speculation that might, in another case, caution this Court to await confirmation of a dispute's true factual contours. The Eleventh Circuit held that a reverse-payment agreement is lawful unless it imposes greater restrictions on generic competition than would a judicial ruling that the brand-name manufacturer's patent is valid and infringed. Because the FTC has not alleged that the agreements at issue in this case are illegal under that standard, no further factual development would assist this Court in determining whether the Eleventh Circuit's approach is correct. To the contrary, the existence of a final judgment on a motion to dismiss makes this case a particularly suitable vehicle for resolving the question presented. See Pet. 30.

Par contends (Br. in Opp. 17-20) that the question presented is unimportant because reverse-payment

agreements are declining when measured as a fraction of all settlements of Hatch-Waxman paragraph IV litigation. The leading brand-name and generic pharmaceutical industry trade groups do not share that perspective, and have filed amicus briefs supporting the *K-Dur* petitions. See Pharm. Research & Mfrs. Amicus Br., *K-Dur*, *supra* (No. 12-245); Generic Pharm. Amicus Ass'n Br., *K-Dur*, *supra* (No. 12-265). And the statistics on which Par relies demonstrate that, although reverse-payment agreements have in some years declined as a *percentage* of overall Hatch-Waxman settlements, the *absolute number* of reverse-payment agreements was twice as great in 2011 as in 2007. See Par Br. in Opp. 19 n.4.

Par posits that this trend is linked to revisions made to the Hatch-Waxman Amendments (see Pet. 3) in 2003 by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), Pub. L. No. 108-173, 117 Stat. 2066. Par states that, under the MMA, the "incentives for reverse-payments are diminished" (Br. in Opp. 24). Par also points out (*id.* at 23-24) that, in briefs filed at this Court's invitation in prior cases, the United States noted the possibility that the MMA might reduce the prevalence of reverse-payment settlements and thereby lessen the continuing practical importance of questions concerning the legality of such agreements.

Since those briefs were filed, however, a clear circuit conflict has developed, and the yearly number of reverse-payment agreements has increased substantially. Par offers no reason to suppose (and no party to either this case or *K-Dur* contends) that the legal standard governing antitrust review of agreements like the ones at issue here and in *K-Dur* should vary depending on whether a generic manufacturer's original abbreviat-

ed new drug application (ANDA) or its paragraph IV certification (see Pet. 4) was submitted before or after the MMA became effective. Absent any impact on the governing legal standard, there is no basis for Par's prediction that "[t]he merits briefs and any ensuing decision in this case would be strewn with digressions about how things used to be pre-MMA." Br. in Opp. 24.

Finally, any marginal benefit that might be achieved by awaiting a case involving an ANDA or paragraph IV certification subject to the MMA is far outweighed by the practical costs associated with deferring review. The existing circuit conflict will create substantial incentives for forum-shopping by all parties until the split is resolved. See Pet. 15. Substantial resources will be wasted litigating under the wrong standard in one circuit or another. If the Eleventh Circuit is correct, brand-name and generic drug manufacturers will be improperly deterred from settling infringement litigation on terms that couple monetary payments from the brand-name to the generic manufacturer with a promise of delayed generic entry. And if the Third Circuit is correct, consumers will continue to suffer serious harm from current and future reverse-payment agreements. Because the MMA amendments affect neither the legal analysis of agreements like the ones at issue here and in *K-Dur* nor whether those agreements are profitable, there is no reason to allow such uncertainty to persist.

B. There Is No Plausible Reason To Deny The FTC's Petition If The *K-Dur* Petitions Are Granted

Par suggests (Br. in Opp. 15) that the FTC's petition should be denied outright even if the *K-Dur* petitions are granted. Absent a jurisdictional or other threshold reason not to entertain the petition—and Par points to none—there is no basis in this Court's certiorari prac-

tice for denying the FTC's petition outright. As a leading treatise explains, "a petition for certiorari may be held * * * until a decision is reached by the Court in a pending case raising identical or similar issues"; "the certiorari papers are held by the Court pending its plenary ruling, following which [a] summary reconsideration order [directed to the court below] is entered." Eugene Gressman et al., *Supreme Court Practice* 339, 346 (9th ed. 2007).

There is, in particular, no merit to Par's suggestion (Br. in Opp. 15, 26-27) that the FTC's petition should be denied simply because the Eleventh Circuit panel issued the decision below before the Third Circuit issued its conflicting decision in *K-Dur*.[1] In the relatively rare situation presented here, where certiorari petitions seeking review of two conflicting court of appeals decisions are simultaneously pending before the Court, nothing in this Court's Rule 10 suggests a preference for reviewing either the earlier or the later of the two decisions. As support for its argument, Par identifies cases in which the Court *granted* review of a decision to resolve a split that developed after the decision under review had been rendered. See *id.* at 26-27 & n.6. Par offers no precedent for what it seeks here—denial of a certiorari petition despite the simultaneous grant of another petition on the same question presented, simply because of the order in which the decisions below were rendered.

Par also suggests (Br. in Opp. 15-16, 26 & n.5) that there was something wrongful about the development of

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[1] The Eleventh Circuit denied rehearing in this case *after* the Third Circuit's issued its decision in *K-Dur*, which the FTC had provided to the Eleventh Circuit under Federal Rule of Appellate Procedure 28(j) while its petition for rehearing was pending.

the circuit conflict here because the FTC and the United States offered amicus presentations that the Third Circuit found persuasive. But the government is not required to accede to the first unfavorable adjudication of an issue in a court of appeals. To the contrary, the government's usual practice—as a party and, *a fortiori*, as an amicus curiae—of relitigating "questions of substantial public importance" in multiple fora ensures that more than one court of appeals can "explore a difficult question before this Court grants certiorari." *United States* v. *Mendoza*, 464 U.S. 154, 160 (1984).[2]

Par also expresses concern (Br. in Opp. 27) that reversal of the Eleventh Circuit's decision would upset expectations that this Court should regard as legitimate. Under our hierarchical judicial system, however, decisions rendered by a lower court are by their nature subject to review and possible reversal by this Court. Par's asserted interest in "repose" (*id.* at 26) is further undermined by the fact that the FTC seeks only declaratory and injunctive relief, rather than damages for the period of time during which the pertinent reverse-payment agreements have been in effect. See Pet. 31-32. If (as the government contends) the Eleventh Circuit erred in treating those agreements as lawful, then Par has already enjoyed the windfall of years of sharing unjust monopoly profits with Solvay. Par's purported reliance interests provide no justification for allowing

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[2] Par speculates that Justice Kagan may be recused from this case by virtue of the FTC's decision to appeal to the Eleventh Circuit during her tenure as Solicitor General. Br. in Opp. 3 n.1. There is no basis for that speculation. The FTC had exclusive authority to commence and supervise the appeal below, 15 U.S.C. 56(a)(2), and it neither requested nor received authorization from the Solicitor General to appeal from the district court's adverse ruling.

those windfall benefits to continue until the agreements expire in 2015.

Par further explains (Br. in Opp. 14) that, during the eight years since the United States first addressed the issue in this Court, the government has refined its position regarding the legal standards that should govern antitrust review of reverse-payment agreements. Of course, private plaintiffs, pharmaceutical-company defendants, and the courts of appeals have done the same. That opportunity for refinement is a signal virtue of this Court's preference for allowing issues to percolate in lower courts, and the culmination of that process is a reason to grant the FTC's petition, not to deny it.

In addition, Par overstates the differences between the government's current legal theory and the positions taken by the United States in prior briefs in this Court. Par emphasizes (Br. in Opp. 14) that the United States urged this Court to deny certiorari in *FTC* v. *Schering-Plough Corp.*, 548 U.S. 919 (2006). The United States' brief in that case, however, did not endorse the scope-of-the-patent rule that Par advocates and that the court below applied. Rather, the United States argued that the Eleventh Circuit's decision in *Schering-Plough* did not foreclose consideration, as part of the antitrust inquiry, of the strength of the underlying infringement suit. See U.S. Br. at 17-19, *Schering-Plough*, *supra* (No. 05-273). The United States further contended that "the interests in consumer welfare protected by the antitrust laws militate against adoption of a legal standard that would facilitate patent holders' efforts to preserve weak patents by dividing their monopoly profits with settling challengers." *Id.* at 10. The following year, in its amicus brief in *Joblove* v. *Barr Labs, Inc.*, 551 U.S. 1144 (2007), the United States criticized the

scope-of-the-patent approach as "insufficiently stringent" and "erroneous," and it stated that "a court reviewing an antitrust challenge to a settlement of a patent infringement claim that includes a reverse payment should apply the rule of reason." U.S. Br. at 8, 12, 13, *Joblove*, *supra* (No. 06-830); see Pet. 21-22 n.6.

C. This Case Is A Superior Vehicle To *K-Dur*

As explained in the FTC's petition (at 29-32), this case is a superior vehicle to *K*-Dur for addressing the question presented. Respondents Watson and Solvay agree. See Watson Br. 28; Solvay Br. 29-31.

1. Par's contrary arguments are insubstantial. First, Par asserts that a "patent surprise" (Br. in Opp. 8-9, 24-25) during Paddock's development of generic AndroGel® makes this antitrust suit atypical. But the fact that Paddock's development efforts were nearly complete when Solvay received its patent is irrelevant to the antitrust question presented. What matters is that once the patent in question issued, the generic manufacturers made paragraph IV certifications to that patent and then entered into reverse-payment agreements with the brand-name manufacturer. In those respects, this case is entirely typical of suits in which reverse-payment agreements have been challenged as anticompetitive.

Second, Par contends that its own situation is unusual because, at the time it settled its litigation against Solvay, existing Eleventh Circuit precedent indicated that the parties' reverse-payment agreement was lawful. Br. in Opp. 14, 26. Nothing in this Court's decisions suggests, however, that an otherwise-impermissible agreement among competitors can be treated as lawful simply because it accords with circuit precedent in effect at the time and place the agreement was made. Par's argu-

ment is particularly misconceived in this civil action for injunctive relief. In such a suit, there is generally neither a scienter element to establishing a violation of the antitrust laws nor a good faith defense to their enforcement. See generally 2 Philip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 303 (3d ed. 2007) (discussing differences among various modes of antitrust enforcement).

Third, Par points out that the district court hearing the patent infringement action against it entered a consent decree in connection with the Par/Solvay settlement agreement (but not in connection with the Watson/Solvay agreement). Br. in Opp. 28-30. Par also makes an intricate argument about the competitive consequences of its status as a second filer (as compared to Watson's status as a first filer). *Id.* at 30-33. Those issues were not addressed by the court of appeals below, and this Court "do[es] not ordinarily address for the first time * * * an issue which the Court of Appeals has not addressed," *J. Truett Payne Co.* v. *Chrysler Motors Corp.*, 451 U.S. 557, 568 (1981).

In any event, those arguments provide no reason to deny the FTC's petition. At the very most, they suggest that Par may have grounds for resisting liability even if the agreement between respondents Watson and Solvay (both of which have urged the Court to grant the FTC's petition) is ultimately found to violate the antitrust laws. If Par is genuinely confident that its agreement is lawful irrespective of the resolution of the question presented, it can inform the Court that it is no longer interested in the case in this Court. Cf. Sup. Ct. R. 12.6.

2. The Court therefore should grant the FTC's petition for a writ of certiorari. The *K-Dur* petitions could then be held pending resolution of this case. In the

alternative, if the Court believes it would benefit from additional briefing focused on *K-Dur*, it could grant all the pending petitions and consolidate the cases. The *K-Dur* respondents advocate the latter course. Br. in Opp. at 17, *K-Dur*, *supra* (No. 12-245). We concur in their view that, if the Court grants all the pending petitions and consolidates the cases, it should substantially expand the time allotted for oral argument in view of the importance and complexity of the legal issues and the factual intricacy of the *K-Dur* record.

The *K-Dur* respondents further "suggest that the Court realign the parties for purposes of briefing" if all the pending petitions are granted. Br. in Opp. at 17, *K-Dur*, *supra* (No. 12-245). We disagree. There may be some force to the *K-Dur* respondents' concern that, if all three pending petitions are granted and the cases are briefed on the standard schedule, "*amicus* participation may be multiplied unnecessarily," *ibid.* (or some amici may strategically delay the filing of their briefs). But if this Court concludes that the two cases are so similar that a single entity's amicus participation in both would be duplicative, it can obviate that concern by granting certiorari in only one case.

On the few recent occasions that we have identified when this Court has granted petitions from opposite sides of a circuit split and consolidated the cases (or ordered them argued in tandem), it has not realigned the parties, but has simply allowed briefing in the normal course. See, *e.g.*, *Hanlon* v. *Berger*, 525 U.S. 981 (1998) (No. 97-1927), consolidated with *Wilson* v. *Layne*, 525 U.S. 981 (1998) (No. 98-83). The *K-Dur* respondents have not advanced a compelling reason to depart from that practice here.

* * * * *

For the foregoing reasons and those stated in the petition for a writ of certiorari, the petition should be granted.

Respectfully submitted.

DONALD B. VERRILLI, JR.
Solicitor General

NOVEMBER 2012

AMICUS CURIAE BRIEF

No. 12-416

SUPREME COURT, U.S.
FILED
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OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

FEDERAL TRADE COMMISSION,

Petitioner,

v.

WATSON PHARMACEUTICALS, INC., *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE STATES OF NEW YORK, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, HAWAII, IDAHO, ILLINOIS, IOWA, KENTUCKY, LOUISIANA, MAINE, MARYLAND, MASSACHUSETTS, MINNESOTA, MISSISSIPPI, NEVADA, NEW HAMPSHIRE, NEW MEXICO, OHIO, OREGON, PENNSYLVANIA, RHODE ISLAND, TENNESSEE, UTAH, VERMONT, WASHINGTON, WEST VIRGINIA, AND WYOMING AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Federal competition law generally prohibits an incumbent firm from agreeing to pay a potential competitor to stay out of the market. *See Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 49-50 (1990). This case concerns agreements between (1) the manufacturer of a brand-name drug on which the manufacturer assertedly holds a patent, and (2) potential generic competitors who, in response to patent-infringement litigation brought against them by the manufacturer, defended on the grounds that their products would not infringe the patent and that the patent was invalid. The patent litigation culminated in a settlement through which the seller of the brand-name drug agreed to pay its would-be generic competitors tens of millions of dollars annually, and those competitors agreed not to sell competing generic drugs for a number of years. Settlements containing that combination of terms are commonly known as "reverse payment" agreements. The question presented is as follows:

Whether reverse-payment agreements are per se lawful unless the underlying patent litigation was a sham or the patent was obtained by fraud (as the court below held) or instead are presumptively anticompetitive and unlawful (as the Third Circuit has held).

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INTEREST OF THE *AMICI*

Amici are the States of New York, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Hawaii, Idaho, Illinois, Iowa, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Nevada, New Hampshire, New Mexico, Ohio, Oregon, Pennsylvania, Rhode Island, Tennessee, Utah, Vermont, Washington, West Virginia and Wyoming.[1] The *Amici* States have strong interests, both as purchasers and as regulators, in protecting fair competition in pharmaceutical markets. Prescription drugs represent a major expenditure for the States, which purchase drugs and make reimbursements for the cost of drugs through state Medicaid and other public health programs and agencies.[2] State Medicaid and local health care programs spent $6.5 billion on prescription drugs in 2010. States also have a recognized interest in enforcing federal antitrust laws, through *parens patriae* standing, to protect their citizens' economic well-being against anticompetitive practices that raise prices and restrict consumer choice.

This case concerns agreements that purport to settle patent disputes, under which a drug patent holder pays money to a would-be generic competitor, and the would-be competitor agrees to delay its entry into the market—described here as "pay-for-delay" agreements. A dispute over the validity or scope of a patent may be appropriately compromised by an agreement that the competitor will enter the market on a date prior to the full term of the

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[1] Counsel of record received timely notice of the States' intent to file this brief, as required by Supreme Court Rule 37.2(a).

[2] The word "purchase" is used in this brief to include purchases and reimbursements.

patent. But when the patent holder pays to delay the entry date of the competitor, monopoly prices prevail for a longer period than is warranted by the uncertain outcome of the patent litigation.

The *Amici* States have a strong interest in vindicating the Federal Trade Commission's position that such agreements presumptively violate the federal antitrust laws.[3] The delay in the entry date of the generic competitor that results from such agreements causes direct and substantial harm to the States and their residents. A recent study shows that pay-for-delay agreements cause drug purchasers nationwide to pay $3.5 billion per year more than they would pay if drug litigation settlements did not include pay-for-delay provisions. As major drug purchasers, the *Amici* States have a strong interest in avoiding those additional costs. And as antitrust enforcers,

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[3] The FTC's claims in this case were brought under the Federal Trade Commission Act, 15 U.S.C. § 45(a); other challenges to similar settlements have been brought under the Sherman Act, 15 U.S.C. § 1. *See, e.g., In re K-Dur Antitrust Litig.*, 686 F.3d 197, 208 (3d Cir. 2012), *petitions for cert. filed*, 81 U.S.L.W. 3090 (Aug. 24, 2012) (No. 12-245); 81 U.S.L.W. 3090 (Aug. 29, 2012) (No. 12-265). The court below decided the case on the assumption that the relevant standards are the same under the FTC Act and the Sherman Act. *See* Pet. App. 17a n.5. *See also Polygram Holding, Inc. v. FTC*, 416 F.3d 29, 32 (D.C. Cir. 2005) ("[T]he . . . analysis under § 5 of the FTC Act is the same . . . as it would be under § 1 of the Sherman Act."); *FTC v. Motion Picture Adver. Servs. Co., Inc.*, 344 U.S. 392, 395 (1953) (holding that conduct prohibited by Sherman Act automatically violates section 5 of the FTC Act). Thus, the States, which have used the Sherman Act to bring antitrust enforcement actions, *see, e.g., New York v. Aventis S.A.*, No. 01 Civ. 71835 (E.D. Mich. 2001), have an interest in the question presented here.

the *Amici* States have a strong interest in bringing cases that would redress and prevent these harms for the benefit of their residents. *See, e.g., New York v. Aventis S.A.*, No. 01 Civ. 71835 (E.D. Mich. 2001) (state plaintiffs challenging pay-for-delay agreement); *Florida v. Abbott Labs.*, No 01 Civ. 4006 (S.D. Fla. 2002) (same).

STATEMENT

In this antitrust enforcement action, the Federal Trade Commission alleges that the defendants violated federal antitrust law by settling a patent dispute with agreements under which the manufacturer of a brand-name drug, Solvay Pharmaceuticals, paid money to would-be generic competitors, Watson Pharmaceuticals and Paddock Pharmaceuticals, to induce them to agree to delay their entry into the market.

Solvay manufactures and markets AndroGel, a gel formulation of synthetic testosterone that is used to treat low testosterone. (2d Am. Compl. ¶ 31.) Solvay holds a patent for AndroGel; at the time of the settlement agreements at issue, the patent was scheduled to expire in 2020.[4] (*Id.* ¶ 43.) Solvay's patent does not cover the drug's active ingredient: testosterone was first synthesized in 1935 and lost patent protection decades ago. (Pet. App. 10a.) Rather, Solvay's patent relates to a particular gel formulation of the drug. (Pet. App. 10a.)

In 2003, Watson and Paddock separately announced plans to market generic testosterone products that

[4] The patent was later extended to February 2021. (2d Am. Compl. ¶ 43.)

would compete with AndroGel. (Pet. App. 10a-11a.) They each applied to the FDA for approval of their generic products under a provision of the Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585, that affords the first generic challenger of a brand-name drug the right, under certain circumstances, to a 180-day period during which the FDA will not approve other generic versions of the same drug. 21 U.S.C. § 355(j)(5)(B)(iv). Soon after Watson and Paddock filed their applications with the FDA, Solvay sued them for patent infringement. (Pet. App. 11a.) The generics responded that their drugs did not infringe Solvay's patent, and that the patent was invalid in any event. (*See* Pet. App. 12a.)

The parties settled the case. Watson and Paddock agreed to delay their entry until 2015, five years before the patent was scheduled to expire in 2020. (Pet. App. 10a.) Solvay already planned to switch its marketing focus to a substitute testosterone product by 2015 in any event. (2d Am. Compl. ¶¶ 62-63.) In exchange for the generic manufacturers' agreement to delay entry, Solvay agreed to pay Watson between $19 and 30 million annually—calculated based on Solvay's AndroGel profits for the year—and to pay Paddock $10 million per year for six years, and Paddock's affiliate Par Pharmaceuticals an additional $2 million per year. (Pet. App. 12a-13a.) The agreement portrayed these payments as compensation for manufacturing or marketing services provided by Watson and Paddock to Solvay. But Solvay had no need for manufacturing or marketing services from its would-be competitors and did not expect to use them. Indeed, Solvay acknowledged internally that the services had little or no value. (2d Am. Compl. ¶¶ 60-85.)

The FTC filed suit in the United States District Court for the Central District of California to challenge

these agreements under Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. The case was later transferred to the Northern District of Georgia on defendants' motion. *See* Def. Joint Motion to Transfer Venue, ECF No. 44-1 (N.D. Ga. Feb. 27, 2009.)[5]

The FTC asserted that the agreements unlawfully extended Solvay's monopoly on AndroGel—not through the strength of Solvay's patent but through the financial incentives it offered its competitors. (2d Am. Compl. ¶ 111.) The complaint specifically alleged that the payments to the generics made economic sense only as a mechanism for delaying the generics' competition with Solvay. (*Id.* ¶¶ 81-85.) The complaint also alleged that Solvay was unlikely to have succeeded in its patent suit to exclude the generic competition. (*Id.* ¶¶ 86-92.)

The district court dismissed the FTC's complaint for failure to state a claim (Pet. App. 37a), holding that there was no antitrust violation because the settlement agreements excluded only competition that could already have been excluded by the patent itself—if the patent were determined valid and the competing generic products were held to infringe it. (Pet. App. 47a-52a.) The United States Court of Appeals for the Eleventh Circuit affirmed (Pet. App. 1a), holding that in the absence of sham litigation or fraud, a settlement of drug patent litigation does not violate antitrust law as long as "its anticompetitive effects fall within the scope of the exclusionary potential of the patent." (Pet. App. 28a.) The court denied a petition for rehearing or rehearing en banc. (Pet. App. 62a-63a.)

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[5] The State of California originally brought this suit jointly with the FTC in California, but California dismissed its claims after the suit was transferred to Georgia over California's jurisdictional objections.

SUMMARY OF ARGUMENT

This Court should grant the petition for certiora because it squarely presents a legal question of exceptiona nationwide importance on which the courts of appeals ar sharply divided: whether antitrust law is violated whe drug patent litigation is settled by agreements in whic drug patent holders pay their generic competitors to sta out of the market. The Court should grant certiorari t resolve the split and lift the uncertainty that currentl hangs over drug purchasers and drug manufacturer alike on this issue. And the Court should hold that pay for-delay settlements are presumptively anticompetitiv and unlawful. It serves neither the public interest nor th fundamental goals of antitrust law and patent law whe brand-name manufacturers are allowed to immunize the patents from scrutiny by buying off their competitors wit a share of their monopoly profits.

ARGUMENT

I. There is a well-developed circuit split as to whethe pay-for-delay settlements of drug patent disputs should receive scrutiny under federal antitru laws.

Over the last decade, the courts of appeals hav divided over how federal competition laws apply to "pay for-delay" or "reverse-payment" settlement agreement Six circuits have addressed the question, and two majo and diametrically opposed approaches have developed.

The first approach, adopted by the Third Circui regards a payment "from a patent-holder to a gener

patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade." *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 208 (3d Cir. 2012), *petitions for cert. filed*, 81 U.S.L.W. 3090 (Aug. 24, 2012) (No. 12-245); 81 U.S.L.W. 3090 (Aug. 29, 2012) (No. 12-265). Under this approach, pay-for-delay settlements of drug patent litigation presumptively violate antitrust law, and the parties to the settlement may attempt to rebut this presumption by proving that the settlement has procompetitive benefits, or that the payment was not made to induce delayed entry. *Id.* The Sixth and D.C. Circuits—although they have not specifically adopted the exact approach followed by the Third Circuit—have also concluded that pay-for-delay settlements raise serious antitrust concerns.[6]

The other approach, taken by the Eleventh Circuit below and by the Second and Federal Circuits, holds, in sharp contrast, that payments for delayed market entry as part of a drug-patent settlement are essentially immune from antitrust scrutiny, as long as the settlement agreement does not exclude competition beyond the term

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[6] The Sixth and D.C. Circuit decisions analyzed the same agreement—an interim agreement reached during the course of patent litigation, rather than a final settlement agreement—in which the generic competitor agreed not to enter the market during the pendency of the patent litigation. The D.C. Circuit held that an antitrust challenge to the agreement survived a motion to dismiss. *Andrx Pharmaceuticals v. Biovail Corp. Int'l*, 256 F.3d 799, 806-815 (D.C. Cir. 2001). The Sixth Circuit found that the agreement was *per se* illegal under federal antitrust law because it represented "a horizontal agreement to eliminate competition." *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896, 908 (6th Cir. 2003).

and extent of the patent on its face. This approach is sometimes known as the "scope-of-the-patent" test. On this approach, "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary *potential* of the patent." (Pet. App. 28a (emphasis added).) *See also In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006). *But see Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, 604 F.3d 98 (2d Cir. 2010) (per curiam) (expressing serious concerns about the scope-of-the-patent approach); *rehearing en banc denied*, 625 F.3d 779 (2d Cir. 2010) (Pooler, J., dissenting); *cert. denied*, 31 S. Ct. 1606 (2011).

The persistence of this circuit split about the correct treatment of pay-for-delay settlements under federal antitrust law has serious adverse consequences. First and most important, agreements between brand-name drug manufacturers and would-be generic competitors affect consumers in every State. It makes no sense for the same nationwide agreement to be viewed as unlawful in some circuits and not in others under a single federal scheme. And that is precisely the situation right now; two circuit courts have reached different conclusions about the legality under federal antitrust law of the very same nationwide settlement agreement. *Compare K-Dur*, 686 F.3d at 218, *with Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1068 (11th Cir. 2005).

The interests of all parties affected by pay-for-delay settlements—the companies that are parties to the agreements, the government agencies that challenge

those agreements, and the governments and members of the public that purchase drugs whose prices are affected by those agreements—would be served by resolution of the current conflict over their lawfulness. Parties on both sides of the issue have urged this Court to resolve the split: the petition in this case was filed by the FTC, as the federal antitrust enforcer seeking to preserve fair competition and protect the interests of drug purchasers, and petitions were also filed in the *K-Dur* case by pharmaceutical companies seeking to defend their pay-for-delay settlements. *See* Pet. for Certiorari, *Merck v. Louisiana Wholesale Drug Co.*, No. 12-245 (challenging the Third Circuit's decision in *K-Dur*); Pet. for Certiorari, *Upsher-Smith Laboratories v. Louisiana Wholesale Drug Co.*, No. 12-265 (same).

The *Amici* States in particular seek a prompt resolution of the circuit split. The States have standing under federal antitrust law to protect their own proprietary interests. *See, e.g., Massachusetts v. E.P.A.*, 549 U.S. 497, 519 (2007). They also have *parens patriae* standing to protect their quasi-sovereign interest in the economic well-being of their residents. *See* 15 U.S.C. § 15c (affording state attorneys general *parens patriae* standing under the Sherman Act); *Georgia v. Pennsylvania R.R.*, 324 U.S. 439, 447 (1945); *California v. American Stores Co.*, 495 U.S. 271 (1990). States have brought a series of cases challenging conduct that delayed a generic drug's entry, including pay-for-delay settlements. *See, e.g., New York v. Aventis S.A.*, No. 01 Civ. 71835 (E.D. Mich. 2001) (state plaintiffs challenging pay-for-delay agreement); *Florida v. Abbott Labs.*, No. 01 Civ. 4006 (S.D. Fla. 2002) (same). The *Amici* States seek a single rule to govern such cases under federal antitrust law.

II. Pay-for-delay settlements should be presumptively unlawful because they are almost always anticompetitive.

The Court should adopt a presumption that pay-for-delay settlements are anticompetitive and unlawful. The issue presented by these settlements involves the intersection of two bodies of law—antitrust law and patent law—each of which exists to protect the public good, and each of which is fundamentally undermined by pay-for-delay drug settlements. Consequently, such settlements should be given serious antitrust scrutiny, as the rule adopted by the Third Circuit requires.

A. Antitrust law protects the public from anticompetitive practices. A classic form of antitrust violation occurs when one firm preserves a profitable monopoly by paying potential competitors to stay out of the market. *See Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 49-50 (1990). The law forbids this practice because it will often be in a monopolist's economic interests to pay a competitor to stay out of the market, thereby allowing the monopolist to earn surplus monopoly profits at the public's expense by keeping prices artificially high and restricting consumer choice. For this reason, settled law holds that agreements in which an incumbent firm splits "monopoly rents" with a would-be competitor to preserve the incumbent's monopoly constitute per se antitrust violations. *Id.*

The facts of this case—as alleged in the amended complaint and accepted as true on the motion to dismiss—illustrate the way that pay-for-delay settlements of drug patent litigation present just this classic antitrust problem.

The FTC's complaint alleged that payments under the settlement agreements from Solvay to its would-be generic competitors made economic sense only as a mechanism for delaying the generics' competition with Solvay. (2d Am. Compl. ¶¶ 81-85.) And it alleged that Solvay understood and intended this result. The company sought to preserve its AndroGel monopoly until 2015, when it planned to shift its marketing focus to a substitute testosterone product. An internal analysis by Solvay, known as "Project Tulip," concluded that it was worth a substantial payment to keep the generic competition out of the market until 2015—that the expected profits during that period from Solvay's sales of AndroGel at the high prices made possible by the absence of generic competition would exceed, by far more than the payment, the expected profits from sales at the lower volume and competitive price that would be required if the competitors entered the market sooner. (*Id.* ¶¶ 57-59.) Solvay also concluded that without such a payment, the parties would settle on an earlier entry date, based solely on their competing views of the validity of the patent, and the likelihood that it was infringed by the generics. (*Id.* ¶¶ 58-60.) Solvay estimated that if its generic competitors entered the market, it would lose $125 million a year in profits (*id.* ¶ 49)—a figure that greatly exceeded the roughly $30 to 40 million per year Solvay would pay the competitors under the settlements.[7]

Thus, the agreements that kept Solvay's competitors out of the market here were a classic example of a

[7] Under the agreements, Watson received $19-30 million per year as its share of the profits from AndroGel; Par received $10 million per year, and Paddock received $2 million per year. (2d Am. Compl. ¶¶ 66, 77.)

monopoly improperly preserved through anticompetitive payments, at the expense of the public. Indeed, Solvay agreed to pay one of its competitors, Watson, a percentage of its profits from AndroGel, allowing the competitor to directly share in the profits from the monopoly preserved by the settlement. (*Id.* ¶¶ 60-61, 66.) The approach taken by the court below effectively prevents the antitrust laws from regulating such anticompetitive agreements and would permit drug companies, systematically and in case after case, to pay competitors to preserve their monopolies beyond what their patents themselves would allow them to achieve.

B. In addition to violating basic antitrust principles, pay-for-delay settlements of drug patent litigation subvert fundamental principles of patent law. It is a mistake to conclude, as the court below did (Pet. App. 18a), that the purposes of patent law are served by immunizing pay-for-delay drug-patent settlements from antitrust scrutiny. Patent law creates limited monopolies, under carefully delineated circumstances, to encourage innovation for the public good. But patents on products that are not genuinely new, can reasonably be derived from existing products, or otherwise are not legitimately patented, do not reward innovation and do not promote the public interest. Instead, those patents, unless exposed as invalid, lead to an improper monopoly that imposes higher prices on consumers and limits consumer choice, without conferring any public benefit in return. The same is true when a patent holder preserves its monopoly by claiming that the patent is infringed by a competing product when this is not actually so.

This Court has stressed that important public objectives are served when the invalidity or limited scope of a patent is revealed: "It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly." *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892). The Court has likewise recognized "the broad public interest in freeing our competitive economy from the trade restraints which might be imposed by price-fixing agreements stemming from narrow or invalid patents." *Edward Katzinger Co. v. Chicago Metallic Manufacturing Co.*, 329 U.S. 394, 400 (1947); *see also Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 100–01 (1993) (noting the "importance to the public at large of resolving questions of patent validity").

The public policy favoring the testing of patents is particularly strong in the area of pharmaceuticals, where Congress has enacted a special statutory scheme, as part of the Hatch-Waxman Act, to encourage would-be generic competitors to challenge patents on brand-name drugs. H.R. Rep. No. 98–857, pt. 1, at 14, reprinted in 1984 U.S.C.C.A.N. 2647 at 2647. The Hatch-Waxman Act gives generic manufacturers a significant incentive to challenge weak patents, so that consumers can benefit from lower drug prices when patents are weak or invalid. *See* S. Rep. No. 107–167, at 4 (2002). The first manufacturer who challenges a brand-name drug's patent by applying to the FDA for approval of a generic version of the drug can benefit from a 180-day period during which the FDA will not approve other generic versions of the same drug. 21 U.S.C. § 355(j)(5)(B)(iv). Congress sought to encourage challenges to drug patents because it understood that the public interest is strongly served when those patents are

tested in litigation. By contrast, the public interest is not served at all when brand-name manufacturers holding weak or invalid patents are allowed to immunize their patents from scrutiny by buying off their competitors with a share of their monopoly profits.

In this very case, the complaint alleges facts suggesting that Solvay's AndroGel patent may well be invalid, and therefore not a patent that serves the purposes of patent law or promotes the public interest. The patent does not cover the active ingredient in AndroGel, synthetic testosterone, which lost patent protection decades ago. (Pet. App. 10a.) Solvay's AndroGel patent applies primarily to the gel formulation the product uses to deliver synthetic testosterone, and Solvay's generic competitors argued, before they settled the patent litigation, that the gel formulation was an obvious variation on existing methods or formulations and accordingly not patentable. (2d Am. Compl. ¶ 88.) *See* 35 U.S.C. § 103 (an invention is not patentable if the subject matter is obvious). The competitors also argued that their generic drugs would not infringe Solvay's patent because their drugs contained ingredients the patent did not cover, and contained amounts different from what Solvay had patented. (2d Am. Compl. ¶ 88.) And the FTC's complaint in this case alleges that if the underlying patent case had been litigated to conclusion, Solvay's patent would likely have been held not to prohibit competition from the generic drugs. (*Id.* ¶¶ 86-92.)

Despite these allegations, the court below held that the payments for delay embodied in the AndroGel settlement agreements were permitted as a matter of law, because "the patent holder had a 'lawful right to exclude others'

from the market." (Pet. App. 17a, quoting *Valley Drug Co. v. Geneva Pharmaceuticals*, 344 F.3d 1294, 1304 (11th Cir. 2003).) The court's statement, however, assumes a conclusion that may well be false. The court essentially assumed that the patent was valid and that the competing products would have infringed the patent—assumptions that the FTC alleged were incorrect on the facts of this case, and assumptions that are unwarranted as a general rule because challenged patents are frequently found to be invalid or not infringed. According to a study by the FTC, generic competitors that challenge drug patents prevail seventy-three percent of the time. *See* FTC, Generic Drug Entry Prior to Patent Expiration 16 (2002).[8] And empirical research has shown that challenges are more likely when a patent is weak. C. Scott Hemphill and Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. Empirical Legal Stud. 613, 643 (2011). Many of the patents that are the subject of pay-for-delay agreements therefore could not succeed in excluding competition to the full extent that the patents on their faces claim. Yet the approach of the court below—which allows payments that exclude competition to the same extent that is allowed on the face of the patent—enables brand-name drug manufacturers in the aggregate to exclude far more generic competition than their patents themselves, if legitimately tested, could legally exclude.

Thus, the Eleventh Circuit's approach, which effectively immunizes settlements from antitrust scrutiny even where the brand-name drug manufacturer's right to exclude has never been established, fits badly with the

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[8] Available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

realities of drug patent practice. Indeed, the rule would allow every brand-name drug manufacturer to preserve its monopoly, all the way up to the expiration date on the face of the patent, whenever the monopoly profits it would earn from doing so exceed the amount that would be required to pay the generic competitor to go away. In case after case, if this approach were adopted, federal antitrust law will provide no bar to the monopolist's ability to preserve the monopoly for as long as is in its economic interests to preserve it, up to the expiration of the patent.

The Eleventh Circuit ignored the reality that many challenged patents are weak, because it believed that taking this into account would involve a cumbersome inquiry into the merits of the specific underlying patent litigation—that is, into whether the particular patent at issue was valid or infringed. (Pet. App. 33a-36a.) But the Third Circuit's approach does not require "mining through mountains of evidence." (Pet. App. 33a.) The approach simply applies a well-grounded presumption that payments to generic competitors in settlement agreements calling for delayed generic entry are made to induce a delay in competition beyond what the patent—whether strong or weak—would support on its own. *K-Dur*, 686 F.3d at 218. Defendants can rebut the presumption by showing that the payment was not made to induce delay in market entry or resulted in a procompetitive benefit of some kind. *Id.* This analysis does not require the court in the antitrust suit "to make a judgment about the merits of a patent infringement claim." (Pet. App. 35a.)

Drug patent disputes should not generally be settled with payments for delay, because such settlements conflict with basic tenets of both antitrust and patent law and

frustrate a key objective of the Hatch-Waxman Act. This principle leaves ample room for settling drug patent litigation in ways that do not facilitate anticompetitive behavior. No antitrust problem arises when the parties to a drug patent dispute resolve the dispute by negotiating a date on which the would-be generic competitor is permitted to enter the market, without a payment made by the brand-name drug manufacturer to the generic to induce the generic to push the entry date back further than the strength of the patent itself would support. In such a settlement, the interests of the antitrust plaintiff and of the general public are aligned. The generic competitor's incentive is to seek the earliest possible date of entry onto the market, and that is precisely what serves the public interest as well, by maximizing competition and reducing consumers' costs. Consequently, settlements with agreed entry dates, without payments for delay, by their nature carry with them public benefits that are similar to those achieved when drug patent disputes are litigated to decision.

Pay-for-delay settlements are a different story. Pay-for-delay settlements allow the brand-name drug manufacturer to purchase more delay in market competition than would result from a negotiation based on the merits of the patent alone. Contrary to the Eleventh Circuit's reasoning (Pet. App. 17a), pay-for-delay settlements do not merely bar competition that is already barred by the patent—the court's position wrongly assumes the validity of the patent and assumes that the generic product infringes the patent, both of which are in dispute in the litigation that is the subject of the settlement.

By allowing brand-name drug manufacturers to buy exclusion of competition—and to do so all the way up to patent expiration dates when it serves their economic interests—such settlements result in greater monopoly protection than the patents alone could have supported. Because that result leads to exactly the kind of anticompetitive harms that antitrust law seeks to prevent, and also thwarts Congress's policy of promoting challenges to invalid drug patents, this Court should grant certiorari to review and reverse the Eleventh's Circuit's decision.

III. Pay-for-delay settlements cause real and substantial harm to the States and to the public

The question presented by this case has enormous practical significance for consumers of pharmaceutical products, for the national economy, and for the States. Total expenditures on prescription drugs in the United States in 2010 were about $259 billion.[9] In New York alone, about $19 billion was spent on prescription drugs in 2011.[10] The States are major participants in the pharmaceutical market, because they expend funds for prescription drugs through Medicaid and other public

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[9] *See* U.S. Dep't of Health & Hum. Svcs., *National Health Expenditure Accounts: Methodology Paper, 2010*, at 4 (Exhibit 1: National Health Expenditures by Type of Expenditure and Program: Calendar Year 2010), available at http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/dsm-10.pdf.

[10] Kaiser Family Foundation, *Total Retail Sales for Prescription Drugs Filled at Pharmacies, 2011*, available at http://www.statehealthfacts.org/comparemaptable.jsp?typ=4&ind=266&cat=5&sub=66&sortc=1&o=a

health programs. Altogether, state Medicaid programs and local health programs across the country spent $6.5 billion for prescription drugs in 2010.[11]

Pay-for-delay settlements harm drug purchasers, both government health-care programs and consumers alike: such settlements delay the availability of generic drugs and keep drug prices artificially high. A 2010 analysis by the FTC found that pay-for-delay settlements cost drug purchasers $3.5 billion annually. FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 2 (2010).[12] Another empirical study conducted in 2009 estimated that pay-for-delay settlements had cost consumers at least $16 billion since 1993. C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Competition*, 109 Colum. L. Rev. 629, 645, 661 & n.130 (2009). And decisions by the courts of appeals that immunize pay-for-delay settlements from antitrust scrutiny have made pay-for-delay settlements more popular, as the Second Circuit has noted. *Arkansas Carpenters*, 604 F.3d at 109 (noting that pay-for-delay settlements appeared to have become more common after the *Tamoxifen* decision). Thus, judicial protection of pay-for-delay settlements has caused significant and direct harms to consumers, and these harms will continue until meaningful antitrust scrutiny of these agreements is restored on a nationwide basis.

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[11] *See* U.S. Dep't of Health & Hum. Svcs., *National Health Expenditure Accounts*, *supra*, note 9, at 4.

[12] Available at http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.

When generic competitors successfully challenge a brand-name patent, the benefits for consumers and governments that participate in the health-care market are substantial. In general, the availability of a generic substitute for a popular drug has immediate and significant consequences for drug consumers; the average retail price for a brand-name drug in 2007 was $119, while the average price for a generic was about $34, just over one-fourth of the average brand-name price. (2d Am. Compl. ¶ 28.) A successful challenge to the patent for Prozac, for example, resulted in entry of a generic two and a half years before the patent would have expired, saving consumers about $2.5 billion. (*Id.* ¶ 30.)

Litigation that challenges patents is an important check on aggressive patent practices, and patent practices are growing only more aggressive. *See* Hemphill and Sampat, *supra*, at 640-643 (discussing empirical evidence of a rise in weaker patents). Immunizing pay-for-delay settlements will result in the use of patents to maintain improper monopolies at serious cost to consumers, even when those patents are invalid or not infringed by the generic product that the settlement keeps off the market. As noted above, a significant majority of challenges to drug patents that are litigated to conclusion—about seventy-three percent—result in a victory by the generic. *See* FTC, *Generic Drug Entry Prior to Patent Expiration* 16 (2002).[13] Empirical research has also demonstrated that challenges to drug patents are more likely to occur when a patent is legally weak and the case against its validity or infringement is therefore strong. Hemphill and Sampat,

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[13] Available at http://www.ftc.gov/os/2002/07/genericdrug study.pdf.

supra, at 643. For example, drug patents are more likely to be challenged under Hatch-Waxman when they, like the AndroGel patent at issue here, do not cover the active ingredient in a drug, but rather cover its formulation in a particular product or aspects of the way the product delivers the active ingredient. *Id.*

Therefore, drug patents that draw Hatch-Waxman challenges are less likely to represent major innovations of the kind that patent law seeks to reward, and are more likely to represent aggressive claims of rights to exclude competition that are legally tenuous. It is thus especially important not to bar antitrust scrutiny of settlements in which brand-name drug-makers terminate such patent challenges through payments to would-be competitors—settlements that will systematically perpetuate improper monopolies to the detriment of the public.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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JOINT APPENDIX

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In the Supreme Court of the United States

FEDERAL TRADE COMMISSION, PETITIONER

v.

WATSON PHARMACEUTICALS, INC., ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

JOINT APPENDIX
(VOLUME 1)

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CERTIORARI GRANTED: DEC. 7, 2012

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UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 10-12729

FEDERAL TRADE COMMISSION, PLAINTIFF-APPELLANT

v.

WATSON PHARMACEUTICALS, INC., PAR PHARMACCUTICAL COMPANIES, INC., PADDOCK LABORATORIES, INC., SOLVAY PHARMACEUTICALS, INC.

PAR PHARMACCUTICAL COMPANIES, INC., PADDOCK LABORATORIES, INC., DEFENDANTS-COUNTER CLAIMANTS-APPELLEES

FEDERAL TRADE COMMISSION, PLAINTIFF-COUNTER DEFENDANT-APPELLANT

v.

WATSON PHARMACEUTICALS, INC., SOLVAY PHARMACEUTICALS, INC., DEFENDANTS-APPELLEES

Filed: June 15, 2010

DOCKET ENTRIES

DATE	PROCEEDINGS
	* * * * *
6/30/10	CIVIL APPEAL DOCKETED. Notice of ap peal filed by Appellant Federal Trade Com mission on 06/10/2010. Fee Status: Fee No Required.
	* * * * *
7/22/10	JURISDICTIONAL QUESTION issued as t Federal Trade Commission and Paddock La boratories, Inc., Par Pharmaccutical Compa nies, Inc., Solvay Pharmaceuticals, Inc. an WPI.
	* * * * *
7/27/10	Appellant's Brief filed by Appellant Feder Trade Commission. Service date: 07/26/201 by US mail—Attorney for Appellee(s Eakes, Grannon, Rabin, Raptis, Robert Ryan, Singla, Sunshine, Trigg, Valentin Weinberger, York.
7/27/10	Record Excerpts filed by Appellant Feder Trade Commission. Service date: 07/26/201 US mail—Attorney for Appellee(s): Bonde Eakes, Gidley, Grannon, Kent, Rabin, Rapti Roberti, Ryan, Singla, Sunshine, Trigg, Wei berger, York; email—Attorney for Appelle Valentine.
7/27/10	E-Brief Tendered: Appellant brief for Appe lant Federal Trade Commission.

DATE	PROCEEDINGS
8/5/10	Response to Jurisdictional Question filed by Paul James Larkin, Jr. for Appellant Federal Trade Commission, Eric Grannon for Appellees Par Pharmaccutical Companies, Inc. and Paddock Laboratories, Inc., Steven Craig Sunshine for Appellee WPI and Jeffrey I. Weinberger for Appellee Solvay Pharmaceuticals, Inc.
	* * * * *
11/10/10	E-Brief Tendered: Appellee brief for Appellees Paddock Laboratories, Inc. and Par Pharmaccutical Companies, Inc.
11/10/10	Appellee's Brief filed by Appellees Paddock Laboratories, Inc. and Par Pharmaccutical Companies, Inc.. Service date: 11/10/2010 US mail—Attorney for Appellant(s): Albert, DeMille-Wagman, Liebes, Meier, Robertson, Unt, Woodward.
11/12/10	E-Brief Tendered: Appellee brief for Appellee WPI.
11/12/10	Appellee's Brief filed by Appellees Solvay Pharmaceuticals, Inc. and WPI. Deficiencies: Attorney signature. (corrections rcvd 11/19/10) Service date: 11/10/2010 US mail—Attorney for Appellant(s): Albert, DeMille-Wagman, Liebes, Meier, Woodward.—[Edited 11/22/2010 by TLR]
	* * * * *

DATE	PROCEEDINGS
12/3/10	Certificate of Readiness filed as to Appellar Federal Trade Commission.
12/3/10	Record on Appeal filed. Record Part: Plea ings, 11 Vol ROA; Record Part: Exhibits, sealed Envelope
12/15/10	E-Brief Tendered: Reply brief for Appellar Federal Trade Commission.
12/16/10	Reply Brief filed by Appellant Federal Trac Commission. Service 12/15/2010 US mail- Attorney for Appellee(s): Gidley, Granno Raptis, Roberti, Ryan, Sunshine, Trigg, Wei berger, York; email—Attorney for Appelle Valentine.
1/19/11	ORDER: Motion to file appendix filed by A torney Mark G. Trigg for Appellees Par Pha maccutical Companies, Inc. and Paddock L boratories, Inc. is GRANTED. SM
1/19/11	Appendix filed by Attorney Mark G. Trigg f Appellees Par Pharmaccutical Companie Inc. and Paddock Laboratories, Inc.. Servi date: 11/10/2010 US mail—Attorney for A pellant(s): Albert, DeMille-Wagman, Liebe Meier, Woodward; Attorney for Appellee(s Bonder, Eakes, Gidley, Grannon, Kent, Rabi Raptis, Roberti, Ryan, Singla, Sunshin Trigg, Weinberger, York; email—Attorne for Appellee: Valentine.

* * * * *

DATE	PROCEEDINGS
5/13/11	Oral argument held. Oral Argument participants were Lawrence DeMille-Wagman for Appellant Federal Trade Commission, Eric Grannon for Appellees Par Pharmaccutical Companies, Inc. and Paddock Laboratories, Inc. and Jeffrey I. Weinberger for Appellee Solvay Pharmaceuticals, Inc.
	* * * * *
4/25/12	Opinion issued by court as to Appellant Federal Trade Commission. Decision: Affirmed. Opinion type: Published. Opinion method: Signed.
4/25/12	Judgment entered as to Appellant Federal Trade Commission.
	* * * * *
6/11/12	Petition for rehearing en banc filed by Appellant Federal Trade Commission. (ECF: Mark Hegedus)
7/17/12	Supplemental Authority filed by Appellant Federal Trade Commission. Service date: 07/17/2012 US mail—Attorney for Appellees: Bonder, Gidley, Grannon, Kent, Rabin, Raptis, Roberti, Sunshine, Weinberger; email—Attorney for Appellees: Eakes, Singla, Trigg, Valentine, York. (ECF: Mark Hegedus)

DATE	PROCEEDINGS
7/18/12	ORDER: The Petition(s) for Rehearing ar DENIED and no Judge in regular active se vice on the Court having requested that th Court be polled, the Petition(s) for Rehearin En Banc filed by Appellant Federal Trad Commission are DENIED.. [6619216-1]
7/27/12	Mandate issued as to Appellant Feder Trade Commission.

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA (ATLANTA)

No. 1:09-cv-00955-TWT

FEDERAL TRADE COMMISSION, STATE OF CALIFORNIA, PLAINTIFF

v.

WATSON PHARMACEUTICALS, INC., PAR PHARMACEUTICAL COMPANIES, INC., PADDOCK LABORATORIES, INC., SOLVAY PHARMACEUTICALS, INC., DEFENDANTS

PAR PHARMACEUTICAL COMPANIES, INC., PADDOCK LABORATORIES, COUNTER CLAIMANT

v.

FEDERAL TRADE COMMISSION, STATE OF CALIFORNIA, COUNTER DEFENDANTS

Filed: Apr. 10, 2009

DOCKET ENTRIES

DATE	DOCKET NUMBER	PROCEEDINGS
1/27/09		SEALED LODGED COMPLAIN' sought to be filed by Plaintifi Federal Trade Commission, Th State of California. (ghap) [Trans ferred from California Central o 4/10/2009.] (Entered: 02/05/2009)
		* * * * *
1/29/09	4	**REDACTED—PUBLIC VEI SION**SEALED COMPLAIN against Defendants Watson Pharn aceuticals, Inc., Par Pharmaceutic Companies, Inc., Paddock Labor tories, Inc., Solvay Pharmaceutical Inc. (Filing fee $ 350: NO FE REQUIRED), filed by plaintif Federal Trade Commission, Tl State of California. (ghap) Modifie on 2/6/2009 (ds). (ds). [Transferre from California Central (4/10/2009.] (Entered: 02/05/2009)
		* * * * *
2/12/09	8	First Amended Complaint (ma Modified on 2/23/2009 (mat [Transferred from California Ce tral on 4/10/2009.] (Entere 02/17/2009)

DATE	DOCKET NUMBER	PROCEEDINGS
2/12/09	9	Stipulation to place on the public record plaintiffs' Amended Complaint and permanently seal plaintiffs' initial complaint filed on January 29, 2009. (mat) Modified on 2/23/2009 (mat). [Transferred from California Central on 4/10/2009.] (Entered: 02/17/2009)
		* * * * *
2/27/09	44	NOTICE OF MOTION AND Joint MOTION to Transfer Case to Northern District of Georgia filed by Defendant Solvay Pharmaceuticals, Inc.. Motion set for hearing on 3/30/2009 at 10:00 AM before Judge Mariana R. Pfaelzer. (Attachments: # 1 Motion, # 2 Declaration Declaration of Julia York, # 3 Declaration Declaration of Eric Grannon, # 4 Declaration Declaration of Clare Carmichael, # 5 Declaration Declaration of John Roberti, # 6 Exhibit Roberti Exhibit A, # 7 Exhibit Roberti Exhibit B, # 8 Exhibit Roberti Exhibit C, # 9 Exhibit Roberti Exhibit D, # 10 Exhibit Roberti Exhibit E, # 11 Exhibit

DATE	DOCKET NUMBER	PROCEEDINGS
		Roberti Exhibit F, # 12 Exhil Roberti Exh G, # 13 Exhibit Ro erti Exh H, # 14 Exhibit Robe Exh I, # 15 Exhibit Roberti Exh # 16 Exhibit Roberti Exh K, # Exhibit Roberti Exh L, # 18 Exhi it Roberti Exh M, # 19 Exhil Roberti Exh N, # 20 Exhibit Ro erti Exh O, # 21 Exhibit Robe Exh P, # 22 Exhibit Roberti Exh # 23 Exhibit Roberti Exh R, # Exhibit Roberti Exh S, # 25 Exhil Roberti Exh T, # 26 Exhibit Ro erti Exh U, # 27 Exhibit Robe Exh V, # 28 Exhibit Roberti E W, # 29 Exhibit Roberti Exh # 30 Exhibit Roberti Exh Y, # Exhibit Roberti Exh Z, # 32 Exhi it Roberti Exh AA, # 33 Exhil Roberti Exh BB, # 34 Exhibit Ro erti Exh CC, # 35 Exhibit Robe Exh DD) (Richardson, Teri) [Tra sferred from California Central 4/10/2009.] (Entered: 02/27/2009
		* * * * *
3/16/09	53	OPPOSITION to Joint MOTION Transfer Case to Northern Distr

DATE	DOCKET NUMBER	PROCEEDINGS
		of Georgia 44, Joint MOTION to Transfer Case to Northern District of Georgia 45 filed by Plaintiff Federal Trade Commission. (Robertson, J) [Transferred from California Central on 4/10/2009.] (Entered: 03/16/2009)
3/16/09	54	OPPOSITION re: Joint MOTION to Transfer Case to Northern District of Georgia 44 *Opposition of the State of California to Defendants' Joint Motion to Transfer Venue to the Northern District of Georgia Based Upon a Lack of Personal Jurisdiction* filed by Plaintiff The State of California. (Attachments: # 1 Declaration Declaration of Cheryl Johnson in Support of Opposition to Motion to Transfer Venue, # 2 Declaration Declaration of Kathleen Foote in Support of Opposition to Motion to Transfer Venue) (Johnson, Cheryl) [Transferred from California Central on 4/10/2009.] (Entered: 03/16/2009)

* * * * *

DATE	DOCKET NUMBER	PROCEEDINGS
3/23/09	59	REPLY In Support Of Joint M(TION to Transfer Case to Norther District of Georgia 44 filed by D fendant Solvay Pharmaceutical Inc.. (Richardson, Teri) [Transfe red from California Central (4/10/2009.] (Entered: 03/23/2009
3/23/09	60	DECLARATION re Reply (Motic related) 59 *Of Joseph Todisco I Further Support of Joint Motion Transfer Venue to the Norther District of Georgia* filed by Defen ant Solvay Pharmaceuticals, In (Richardson, Teri) [Transferr from California Central (4/10/2009.] (Entered: 03/23/2009)
3/23/09	61	DECLARATION of Scott Tarriff Reply (Motion related) 59 *in Fu ther Support of Joint Motion Transfer Venue to the Norther District of Georgia* filed by Defen ant Solvay Pharmaceuticals, In (Richardson, Teri) [Transferr from California Central (4/10/2009.] (Entered: 03/23/2009
3/23/09	62	DECLARATION of Julia K. Yo re Reply (Motion related) 59

DATE	DOCKET NUMBER	PROCEEDINGS
		Support of Defendants' Joint Motion to Transfer Venue filed by Defendant Solvay Pharmaceuticals, Inc.. (Richardson, Teri) [Transferred from California Central on 4/10/2009.] (Entered: 03/23/2009)
3/23/09	63	DECLARATION of David A. Buchen re Reply (Motion related) 59 *In Support of Defendants' Joint Motion to Transfer Venue to the Northern District of Georgia* filed by Defendant Solvay Pharmaceuticals, Inc.. (Richardson, Teri) [Transferred from California Central on 4/10/2009.] (Entered: 03/23/2009)
3/23/09	64	DECLARATION of Vera Nackovic re Reply (Motion related) 59 *In Support of Defendants' Joint Motion to Transfer Venue to the Northern District of Georgia* filed by Defendant Solvay Pharmaceuticals, Inc.. (Richardson, Teri) [Transferred from California Central on 4/10/2009.] (Entered: 03/23/2009)
3/23/09	65	DECLARATION of Vera Nackovic (part 2 of 2) re Reply (Motion related) 59, Declaration (non-motion) 64

DATE	DOCKET NUMBER	PROCEEDINGS
		In Support of Defendants' Joi *Motion to Transfer Venue to t* *Northern District of Georgia* file by Defendant Solvay Pharmaceut cals, Inc.. (Richardson, Teri) [Tra sferred from California Central (4/10/2009.] (Entered: 03/23/2009
		* * * * *
4/6/09	69	NOTICE OF MOTION AND M(TION to Dismiss Case filed by D fendant Par Pharmaceutical Cor panies, Inc., Paddock Laboratorie Inc.. Motion set for hearing (5/11/2009 at 10:00 AM before Judg Mariana R. Pfaelzer. (Attachment # 1 Notice of Motion, # 2 Declar tion of Eric Grannon, # 3 Exhibi to Declaration of Eric Grannon, # Proposed Order) (Grannon, Eri [Transferred from California Ce tral on 4/10/2009.] (Entere 04/06/2009)
4/6/09	70	NOTICE OF MOTION AND Joi MOTION to Dismiss Case filed l Defendant Watson Pharmaceutica Inc.. Motion set for hearing (5/11/2009 at 10:00 AM before Judg

DATE	DOCKET NUMBER	PROCEEDINGS
		Mariana R. Pfaelzer. (Attachments: # 1 Joint Notice of Motion, # 2 Declaration Declaration of Julia K. York In Support of Defendants' Joint Motion to Dismiss Plaintiffs' First Amended Complaint, # 3 Exhibit A, # 4 Exhibit B, # 5 Exhibit C, # 6 Exhibit D, # 7 Exhibit E, # 8 Exhibit F, # 9 Exhibit G, # 10 Exhibit H, # 11 Exhibit I, # 12 Exhibit J, # 13 Proposed Order [Proposed] Order, # 14 Proof of Service) (Adler, Douglas) [Transferred from California Central on 4/10/2009.] (Entered: 04/06/2009)
4/8/09	71	ORDER TRANSFERRING CASE by Judge Mariana R. Pfaelzer transferring case to Northern District of Georgia. (MD JS-6. Case Terminated.) (es) [Transferred from California Central on 4/10/2009.] (Entered: 04/06/2009)
		* * * * *
4/21/09	87	ANSWER to COMPLAINT (Discovery ends on 1/19/2010), COUNTERCLAIM *to Plaintiff's First Amended Complaint* against all

DATE	DOCKET NUMBER	PROCEEDINGS
		plaintiffs by Par Pharmaceutic Companies, Inc., Paddock Labor tories, Inc.. (Trigg, Mark) Plea visit our website at http://ww gand.uscourts.gov to obtain Pretri Instructions. Modified caps/dupli ative text on 4/22/2009 (dr). (E tered: 04/21/2009)
		* * * * *
4/21/09	94	Notice of Dismissal Without Pr judice by The State of California claims against Watson Pharmace ticals, Inc., Par Pharmaceutical C mpanies, Inc., Paddock Laborat ries, Inc. and Solvay Pharmaceu cals, Inc. pursuant to FRC 41.a.1.A (dr) (Entered: 04/22/200
		* * * * *
5/28/09	114	Second AMENDED COMPLAIN against all defendants, filed by Fe eral Trade Commission. (Attac ments: # 1 Exhibit) (Liebes, Cind Please visit our website at http www.gand.uscourts.gov to obta Pretrial Instructions. (Entere 05/28/2009)

DATE	DOCKET NUMBER	PROCEEDINGS
5/28/09	115	Unopposed MOTION to Seal *Temporarily Exhibit A to FTC'S Second Amended Complaint and to Set Briefing Schedule for Motion for Protective Order* by Federal Trade Commission. (Attachments: #1 Text of Proposed Order, #2 Exhibit) (Liebes, Cindy) (Additional attachment(s) added on 05/28/2009: #3 Exhibit A Filed Under Seal) (dr). Modified/verified by ryc Exhibit A on 05/28/2009 (dr). (Entered: 05/28/2009)
6/2/09	116	ORDER granting 115 Motion to Seal Temporarily Exhibit A to FTC's Second Amended Complaint. Signed by Judge Thomas W. Thrash, Jr on 6/1/09. (dr) (Entered: 06/02/2009)
6/5/09	117	MOTION for Protective Order with Brief In Support by Solvay Pharmaceuticals, Inc.. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D, # 5 Text of Proposed Order) (Bonder, Teresa) (Entered: 06/05/2009)

* * * * *

DATE	DOCKET NUMBER	PROCEEDINGS
6/15/09	121	MOTION to Stay *Proceedings* Federal Trade Commission. (A tachments: # 1 Text of Propos Order, # 2 Exhibit Declaration Erin C. Burns) (Liebes, Cindy) (F tered: 06/15/2009)
6/17/09	122	RESPONSE in Opposition re 1 MOTION to Stay *Proceedings* fil by Watson Pharmaceuticals, Ir Par Pharmaceutical Compani Inc., Paddock Laboratories, Ir Solvay Pharmaceuticals, Inc. (A tachments: # 1 Declaration, # 2 E hibit Index, # 3 Exhibit A, # 4 E hibit B, # 5 Exhibit C, # 6 Exhi D, # 7 Exhibit E, # 8 Exhibit F, # Exhibit G, # 10 Exhibit H, # 11 E hibit I, # 12 Exhibit J, # 13 Exhi K, # 14 Exhibit L, # 15 Exhibit # 16 Exhibit N, # 17 Text of P posed Order) (Bonder, Teresa) (F tered: 06/17/2009)
6/17/09	123	RESPONSE re 117 MOTION Protective Order filed by Fede Trade Commission. (Attachmen # 1 Affidavit Bradley S. Albert, # Exhibit A, # 3 Exhibit B, # 4 E

DATE	DOCKET NUMBER	PROCEEDINGS
		hibit C, # 5 Exhibit D, # 6 Exhibit E, # 7 Exhibit F, # 8 Exhibit G, # 9 Exhibit H, # 10 Exhibit I, # 11 Exhibit J, # 12 Exhibit K) (Robertson, John) (Entered: 06/17/2009)
6/22/09	124	ANSWER to 87 Counterclaim *of Par and Paddock* by Federal Trade Commission (Robertson, John) Please visit our website at http://www.gand.uscourts.gov to obtain Pretrial Instructions. (Entered: 06/22/2009)
6/26/09	125	REPLY BRIEF re 117 MOTION for Protective Order filed by Solvay Pharmaceuticals, Inc.. (Attachments: # 1 Exhibit A, # 2 Exhibit B) (Bonder, Teresa) (Entered: 06/26/2009)
		* * * * *
7/6/09	128	REPLY BRIEF re 121 MOTION to Stay *Proceedings* filed by Federal Trade Commission. (Attachments: # 1 Affidavit Llewellyn O. Davis, # 2 Exhibit A, # 3 Exhibit B, # 4 Exhibit C, # 5 Exhibit D, # 6 Exhibit E) (Robertson, John) Modified on 7/8/2009 to correct text to accu-

DATE	DOCKET NUMBER	PROCEEDINGS
		rately reflect efiled pleading (tcc (Entered: 07/06/2009)
7/8/09		Submission of 117 MOTION fc Protective Order, 121 MOTION t Stay *Proceedings*, submitted to Di trict Judge Thomas W. Thrash. (d (Entered: 07/08/2009)
		* * * * *
7/20/09	130	MOTION to Dismiss with Brief I Support by Watson Pharmaceu icals, Inc., Solvay Pharmaceutical Inc.. (Attachments: # 1 Brie (Bonder, Teresa) (Entere 07/20/2009)
7/20/09	131	MOTION to Dismiss *The Secon Amended Complaint* with Brief I Support by Par Pharmaceutic Companies, Inc., Paddock Labor tories, Inc., Par Pharmace tical Companies, Inc., Paddo Laboratories, Inc.. (Attachment # 1 Brief in Support of Defe dants Par Pharmaceutical Comp nies, Inc. and Paddock Labo atories, Inc.'s Motion to Di miss the Second Amended Cor plaint, # 2 Exhibit, # 3 Text of Pr

DATE	DOCKET NUMBER	PROCEEDINGS
		posed Order) (Trigg, Mark) (Entered: 07/20/2009)
		* * * * *
8/21/09	137	RESPONSE in Opposition re 131 MOTION to *Dismiss The Second Amended Complaint*, 130 MOTION to Dismiss filed by Federal Trade Commission. (Attachments: # 1 Exhibit 1, # 2 Exhibit 2, # 3 Exhibit 3, # 4 Exhibit 4, # 5 Exhibit 5) (Robertson, John) (Entered: 08/21/2009)
		* * * * *
9/11/09	139	REPLY BRIEF re 130 MOTION to Dismiss filed by Watson Pharmaceuticals, Inc., Solvay Pharmaceuticals, Inc.. (Attachments: # 1 Exhibit Index, # 2 Exhibit A, # 3 Exhibit B) (Bonder, Teresa) (Entered: 09/11/2009)
9/11/09	140	RESPONSE in Support re 131 MOTION to Dismiss *The Second Amended Complaint* filed by Par Pharmaceutical Companies, Inc., Paddock Laboratories, Inc., Par Pharmaceutical Companies, Inc., Paddock Laboratories, Inc.. (At-

DATE	DOCKET NUMBER	PROCEEDINGS
		tachments: # 1 Exhibit C, # 2 Ex hibit D) (Trigg, Mark) (Entered 09/11/2009)
9/22/09		Submission of 130 MOTION to Dis miss, 131 MOTION to Dismiss *Th Second Amended Complaint*, sub mitted to District Judge Thomas W Thrash. (dr) (Entered: 09/22/2009
		* * * * *
1/7/10	152	Minute Entry for proceedings hel before Judge Thomas W. Thrash Jr: Motion Hearing held o 1/7/2010. The Court heard argu ment from counsel on pending mo tions to dismiss and took the matte under advisement and will issue written order as soon as possible Associated Cases: 1:09-md-02084 TWT et al. (Court Reporter Susa Baker) (fap) (Entered: 01/08/2010
2/22/10	153	ORDER granting (8), (9), (22), (23 Motion to Dismiss as to the claim of the FTC and the Indirect Pur chasers, granting in part and deny ing in part (24), (25), (26), (27), (28 (29) Motion to Dismiss as to th claims of the Direct Purchasers i

DATE	DOCKET NUMBER	PROCEEDINGS
		case 1:09-md-02084-TWT; granting (130) Motion to Dismiss; granting (131) Motion to Dismiss in case 1:09-cv-00955-TWT; granting in part and denying in part (124) Motion to Dismiss; granting in part and denying in part (125) Motion to Dismiss in case 1:09-cv-00956-TWT; granting in part and denying in part (134) Motion to Dismiss; granting in part and denying in part (135) Motion to Dismiss in case 1:09-cv-00957-TWT; granting in part and denying in part (127) Motion to Dismiss; granting in part and denying in part (128) Motion to Dismiss in case 1:09-cv-00958-TWT; granting in part and denying in part (62) Motion to Dismiss; granting in part and denying in part (63) Motion to Dismiss in case 1:09-cv-02776-TWT; granting (62) Motion to Dismiss; granting (63) Motion to Dismiss in case 1:09-cv-02848-TWT; granting in part and denying in part (79) Motion to Dismiss; granting in part and denying in part (80) Motion to Dismiss in case 1:09-cv-02913-TWT; granting

DATE	DOCKET NUMBER	PROCEEDINGS
		(59) Motion to Dismiss; grantin (60) Motion to Dismiss in case 1:0 cv-02914-TWT; granting (59) Motio to Dismiss; granting (60) Motion t Dismiss in case 1:09-cv-02915-TWT granting in part and denying in pa (61) Motion to Dismiss; granting i part and denying in part (62) Motio to Dismiss in case 1:09-cv-0301 TWT. Signed by Judge Thomas W Thrash, Jr on 2/22/10. Associate Cases: 1:09-md-02084-TWT et a (dr) (Entered: 02/23/2010)
2/23/10	154	ORDER granting 117 Motion fo Protective Order. Signed by Judg Thomas W. Thrash, Jr on 2/23/1 (dr) (Entered: 02/24/2010)
4/16/10	155	MOTION for Judgment by Feder Trade Commission. (Attachment # 1 Text of Proposed Order) (A bert, Bradley) (Entered: 04/16/201
4/20/10	156	ORDER granting 155 Motion fo Entry of Judgment pursuant t Fed. R. Civ. P. 58(D). Signed b Judge Thomas W. Thrash, Jr o 4/19/10. (dr) (Entered: 04/21/201

DATE	DOCKET NUMBER	PROCEEDINGS
4/21/10	157	CLERK'S JUDGMENT that pursuant to Fed.R.Civ.P.58 the Federal Trade Commission's claims are dismissed with prejudice. (dr)—Please refer to http://www.ca11.uscourts.gov to obtain an appeals jurisdiction checklist—(Entered: 04/21/2010)
5/26/10		Civil Case Terminated. (dr) (Entered: 05/26/2010)
6/10/10	158	NOTICE OF APPEAL as to 156, order 157 Clerk's Judgment by Federal Trade Commission. Transcript Order Form due on 6/24/2010 (Albert, Bradley) Modified on 6/11/2010 to link order appealed. (fem). (Entered: 06/10/2010)
		* * * * *
8/3/10	162	STIPULATION of Dismissal With Prejudice of the Counterclaim of Defendants Paddock Laboratories, Inc., Par Pharmaceutical Companies, Inc.. (Grelecki, Ryan) Modified on 8/4/2010 to correct duplicate text. (cem) (Entered: 08/03/2010)

DATE	DOCKET NUMBER	PROCEEDINGS
8/4/10		Clerk's Entry of Dismissal AP PROVING 162 Stipulation of Dis missal with prejudice of the couter claim pursuant to Fed. R. Civ P. 41(a)(1)(ii). (cem) (Entered 08/04/2010)
		* * * * *
4/25/12	173	USCA Opinion received re: 158 No tice of Appeal filed by Federa Trade Commission. In accordanc with FRAP 41(b), the USCA man date will issue at a later date. Cas Appealed to USCA Case Numbe 10-12729. (fem) (Entered 04/25/2012)
		* * * * *
7/27/12	174	Certified copy of JUDGMENT c USCA AFFIRMING the decision c the District Court re 173 USC Opinion re: 158 Notice of Appe filed by Federal Trade Commissio Case Appealed to USCA Case Num ber 10-12729. (fem) (Entered 07/27/2012)

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA ATLANTA DIVISION

Civil Action
File No. 1:09-CV-00955-TWT

FEDERAL TRADE COMMISSION, ET AL., PLAINTIFF

v.

WATSON PHARMACEUTICALS, INC., ET AL., A CORPORATION; PAR PHARMACEUTICAL COMPANIES, INC., A CORPORATION; PADDOCK LABORATORIES, INC., A CORPORATION; AND SOLVAY PHARMACEUTICALS, INC., A CORPORATION, DEFENDANTS

Filed: May 28, 2009

SECOND AMENDED COMPLAINT FOR INJUNCTIVE AND OTHER EQUITABLE RELIEF

Plaintiff, the Federal Trade Commission (FTC), by its designated attorneys, petitions this Court, pursuant to Section 13(b) of the Federal Trade Commission Act, 15 U.S.C. § 53(b) (2005), for a permanent injunction against defendants Watson Pharmaceuticals, Inc., Par Pharmaceutical Companies, Inc., Paddock Laboratories, Inc., and Solvay Pharmaceuticals, Inc., to undo and prevent their unfair methods of competition in or affecting

commerce in violation of Section 5(a) of the Federa Trade Commission Act, 15 U.S.C. § 45(a).

I. Nature of the Case

1. This case challenges agreements by Watson, Par and Paddock to delay until 2015 the sale of low-cost ge neric versions of AndroGel, a widely prescribed brande testosterone replacement drug, in exchange for substan tial payments from Solvay.

2. By 2006, AndroGel had grown to be Solvay's top selling pharmaceutical product, with U.S. sales of ove $300 million. The prospect of generic competition, how ever, threatened Solvay's AndroGel profits. Severa years earlier, Watson and Paddock (which then part nered with Par) had filed applications with the U.S. Foo and Drug Administration to market generic versions c AndroGel, and by early 2006 Watson had received fina approval to market its generic product. Defendant knew that if generic entry were to occur, Solvay's sale would plummet, as generic AndroGel would be price dramatically lower than branded AndroGel. Solvay' loss, however, would be consumers' gain, as they woul save hundreds of millions of dollars by purchasing low er-cost generic alternatives.

3. After Watson and Paddock had announced thei plans to sell generic AndroGel, Solvay sued the generi companies for infringing the only patent Solvay had re lating to AndroGel. In the ensuing litigation, each of th generic companies vigorously asserted that its produc was outside the scope of Solvay's patent, that the pater was invalid, and that Solvay withheld important infor

mation from the Patent and Trademark Office in obtaining the patent. Had the patent suit proceeded, Solvay's patent was unlikely to prevent generic entry.

4. Eventually, Defendants recognized that they would each be better off by cooperating and sharing in Solvay's monopoly profits than by competing. Solvay's own financial analysis highlighted this dynamic. From this analysis, Solvay knew that it would need to pay the generic firms to agree to stay off the market until 2015, Solvay's desired generic entry date. At the same time, Solvay knew that—because eliminating price competition would preserve its monopoly profits—it could easily afford to pay the generic firms to delay their entry until 2015.

5. In the end, Watson, Par, and Paddock agreed to share in Solvay's monopoly profits, abandon their patent challenges, and refrain from launching their low-cost generic products to compete with AndroGel for nine years. Together with Solvay, they also identified ways to transfer the money to the generic firms: via co-promotion arrangements and a back-up supply deal executed on the same day as the companies' patent settlements.

6. As a result of Defendants' agreements, Watson and Par, rather than competing against Solvay, are partnering with Solvay to promote AndroGel and share in monopoly profits—with expected payments of hundreds of millions of dollars collectively. Solvay's substantial payments to Watson, Par, and Paddock—not the strength of Solvay's patent—have prevented generic competition to AndroGel until 2015. These agreements

deny consumers the opportunity to purchase lower-cost, generic versions of AndroGel, at a cost of hundreds of millions of dollars a year.

II. Jurisdiction and Venue

7. This Court has subject matter jurisdiction over this action pursuant to 15 U.S.C. §§ 45(a) and 53(b), and 28 U.S.C. §§ 1331, 1337(a), and 1345

8. This Court has personal jurisdiction over each Defendant pursuant to 15 U.S.C. § 53(b), and because each Defendant has the requisite constitutional contacts with the United States of America.

9. Venue in this district is proper under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c), and under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b). Each Defendant resides, transacts business, committed an illegal or tortious act, or is found in this District.

10. Defendants' general business practices, and the unfair methods of competition alleged herein, are "in or affecting commerce" within the meaning of Section 5 of the FTC Act, 15 U.S.C. § 45.

11. Each Defendant is, and at all times relevant herein has been, a corporation, as "corporation" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

III. The Parties

12. Plaintiff Federal Trade Commission is an administrative agency of the United States government, established, organized, and existing pursuant to the FTC Act 15 U.S.C. § 41 *et seq.*, with its principal offices in Wash-

ington, D.C. The FTC is vested with authority and responsibility for enforcing, *inter alia*, Section 5 of the FTC Act, 15 U.S.C. § 45, and is authorized under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), to initiate court proceedings to enjoin violations of any law the FTC enforces.

13. Defendant Watson Pharmaceuticals, Inc. (together with its affiliates, "Watson") is a publicly traded, for-profit company, incorporated in Nevada and with its principal place of business located in Corona, California. Watson is engaged in the business of, among other things, developing, manufacturing, marketing, and distributing generic drug products. In the twelve months ending December 31, 2007, Watson had net revenues of approximately $2.5 billion.

14. Defendant Par Pharmaceutical Companies, Inc. (together with its affiliates, "Par") is a publicly traded, for-profit company, incorporated in Delaware and with its principal place of business located in Woodcliff Lake, New Jersey. Par is engaged in the business of, among other things, developing, manufacturing, marketing, and distributing generic drug products. In the twelve months ending December 31, 2007, Par had total revenues of approximately $770 million.

15. Defendant Paddock Laboratories, Inc. (together with its affiliates, "Paddock") is a privately held, for-profit company, incorporated in Minnesota and with its principal place of business located in Minneapolis, Minnesota. Paddock is engaged in the business of, among other things, developing, manufacturing, marketing, and distributing generic drug products.

16. Defendant Solvay Pharmaceuticals, Inc. (together with its affiliates, "Solvay") is incorporated in Georgia and has its principal place of business in Marietta, Georgia. Solvay Pharmaceuticals is a subsidiary of Solvay, S.A., a Belgian company whose shares are listed on the Euronext Brussels stock exchange and traded over-the-counter in the United States via American Depositary Receipts. Solvay includes Unimed Pharmaceuticals, Inc., Solvay's wholly owned subsidiary. Solvay is engaged in the distribution and sale of branded pharmaceutical products, including AndroGel. In the twelve months ending December 31, 2007, Solvay's U.S. net pharmaceutical revenues totaled about $1.2 billion, over $400 million of which were U.S. sales of AndroGel.

IV. Background

A. The regulatory system governing pharmaceuticals in the United States

17. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e), establishes procedures designed to facilitate competition from lower-priced generic drugs, while maintaining incentives for pharmaceutical companies to invest in developing new drugs.

18. A company seeking approval from the U.S. Food and Drug Administration ("FDA") to market a new drug (*i.e.*, a branded drug) must file a New Drug Application

("NDA") demonstrating the safety and efficacy of its product.

19. An "AB-rated" generic drug is one that the FDA has determined to be bioequivalent to a branded drug. A generic drug is considered bioequivalent to a branded drug if it contains the same active pharmaceutical ingredient as the branded drug and there is no significant difference in the quality, safety, and efficacy of the two drugs.

20. A company seeking to market an "AB-rated" generic version of a branded drug must also file an application with the FDA, but may file an Abbreviated New Drug Application ("ANDA").

21. When a branded drug is covered by one or more patents, a generic drug company that intends to market its generic drug prior to expiration of any patents may proceed to seek FDA approval, but must certify in the ANDA that either (1) the generic version does not infringe the patents on the brand-name drug, or (2) the patents are invalid. This is referred to as a "paragraph IV certification."

22. If a generic drug company makes a paragraph IV certification, it must notify the patent holder of the filing of its ANDA. If the patent holder initiates a patent infringement suit against the generic drug company within 45 days of receiving such notice, the FDA may not grant final approval of the ANDA for the generic drug until the earliest of (1) patent expiry, (2) district court resolution of the patent litigation in favor of the generic

company, or (3) the expiration of an automatic 30-month waiting period.

23. The Hatch-Waxman Act gives the first generic company filing an ANDA containing a paragraph IV certification a period of protection from competition with other generic versions of the drug. As to drugs for which the first paragraph IV filing was made before December 2003, as is the case here, the FDA may not approve other generic versions of the same drug until 180 days after the earlier of the date on which (1) the first company begins commercial marketing of its generic version of the drug, or (2) an appeals court finds the patent(s) claiming the branded drug invalid or not infringed. This is referred to as "180-day exclusivity."

B. The consumer benefits of generic drugs

24. Although therapeutically the same as its branded counterpart, the first AB-rated generic equivalent to a branded drug is typically priced significantly lower than the brand. Upon the entry of additional AB-rated generic drugs, generic drug prices generally fall even more.

25. Because of these price advantages, states encourage generic competition through laws that allow pharmacists to dispense an AB-rated generic drug when presented with a prescription for its branded equivalent unless a physician or the patient directs otherwise. These state laws facilitate substitution of lower-priced AB-rated generic drugs for higher-priced branded drugs.

26. Many third party payers of prescription drugs (*e.g.*, health insurance plans, Medicaid programs) have adopted policies to encourage the substitution of AB-rated generic drugs for their branded counterparts.

27. As a result of lower prices and the ease of substitution, many consumers routinely switch from a branded drug to an AB-rated generic drug upon its introduction. Consequently, AB-rated generic drugs typically capture a significant share of their branded counterparts' sales, causing a significant reduction of the branded drugs' unit and dollar sales.

28. Competition from generic drugs generates large savings for consumers. A 1998 Congressional Budget Office Report estimates that in 1994 alone, purchasers saved $8 to $10 billion on prescriptions at retail pharmacies by purchasing generic drugs instead of the equivalent branded drugs. A 2004 FDA study calculates that patients could reduce the daily costs of their medications by more than 50 percent by purchasing generic drugs when available. According to the National Association of Chain Drug Stores, the average retail price for a brand-name prescription was about $119 in 2007, while the average retail price for a generic prescription was about $34.

29. Significant consumer savings can result when generic companies successfully challenge patents and enter prior to patent expiration. For example, a generic company's successful challenge invalidating a patent covering the antidepressant drug Prozac resulted in generic entry 2½ years before patent expiry and about $2.5 billion in estimated consumer savings. A successful

challenge invalidating patents covering the cancer drug Taxol resulted in generic entry over 11 years before patent expiry and estimated consumer savings of more than $3.5 billion.

30. There are many other examples of successful patent challenges by generic drug companies. Indeed, empirical studies have shown that when pharmaceutical patent infringement claims are tested in the courts, the alleged infringer prevails in the majority of cases. An analysis of Federal Circuit decisions from 2002 through 2004 in which the court made a final ruling on the merits of a pharmaceutical patent claim (validity, infringement, or enforceability) found that the alleged infringers had a success rate of 70 percent. An FTC study of all patent litigation initiated between 1992 and 2000 between brand-name drug manufacturers and Paragraph IV generic applicants found similar results: when cases were litigated to a decision on the merits, the generics prevailed in cases involving 73 percent of the challenged drug products.

C. Solvay's AndroGel prescription drug

31. Solvay markets a branded prescription drug called AndroGel. AndroGel is a pharmaceutical gel containing synthetic testosterone. Testosterone was first artificially synthesized in 1935 and has been available in various drug products since the 1950s. Pharmaceutical gel products have also been available for decades.

32. In August 1995, Solvay licensed the U.S. rights to the testosterone gel formulation used for AndroGel from the Belgian pharmaceutical company Besins Healthcare

S.A. (together with its affiliates, "Besins"), which had developed the formulation. At the same time, Besins agreed to provide commercial supply of AndroGel to Solvay after the FDA approved the product for sale.

33. Solvay filed a U.S. New Drug Application for AndroGel in April 1999, which the FDA approved in February 2000. AndroGel is approved for testosterone replacement therapy in men with low testosterone. Low testosterone is often associated with advancing age, certain cancers, diabetes, and HIV/AIDS, among other conditions, and can result in fatigue, muscle loss, and erectile dysfunction.

34. Solvay's sales of AndroGel have grown substantially over time. In 2000, U.S. AndroGel sales were approximately $26 million. By 2003, U.S. sales had grown to about $277 million. By 2007, U.S. AndroGel sales were over $400 million.

35. From 2000 through 2007, cumulative U.S. sales of AndroGel were over $1.8 billion. These sales substantially exceeded Solvay's costs of developing AndroGel.

36. AndroGel has consistently been Solvay's highest-selling product. In 2007, sales of AndroGel accounted for about one third of Solvay's U.S. pharmaceutical revenues.

37. Solvay sells AndroGel at prices far above Solvay's cost of obtaining the product from Besins, making AndroGel highly profitable for Solvay. Even accounting for other direct expenses Solvay allocates to selling and marketing AndroGel, Solvay's profit margin on AndroGel net sales is substantial.

D. Solvay's formulation patent

38. Testosterone, the hormone contained in Andro Gel, is unpatented. Patents covering the synthesis o artificial testosterone expired decades ago.

39. In August 2000, five years after Solvay license AndroGel from Besins, Solvay and Besins employee applied for a U.S. patent relating to AndroGel. The pa tent did not claim testosterone itself or methods of usin testosterone generally, but rather covered the use of particular pharmaceutical gel formulation containin testosterone and other specified ingredients in certai amounts.

40. As described in a report by the United State Government Accountability Office, patent examiners ar generally expected to process an average of 87 paten applications per year and have time quotas of a total o 19 hours to process each application from its filin through its final acceptance or rejection. These tim quotas are reinforced by examiners' bonus compensa tion, which is largely tied to the number of application processed to completion. The patent application proces is an ex parte process in which patent examiners rel upon the information and candor of applicants. The vas majority of all patent applications are ultimately grant ed.

41. In prosecuting the patent application relating t AndroGel, Solvay submitted to the patent examiner mu tiple disclosure statements identifying more than 40 articles and patents discussing previous testosteron and hormone therapies, together with copies of each c

these hundreds of articles and patents in multiple notebooks, comprising more than three feet of materials for the examiner to attempt to review. In addition, Solvay filed more than 240 additional pages of papers, responses, amendments, and declarations.

42. The patent Solvay prosecuted issued on January 7, 2003 as Patent No. 6,503,894 (the "formulation patent"). Five months later, Solvay requested that the Patent and Trademark Office "correct" many claims of the formulation patent—claims originally requested and advocated by Solvay—by inserting a scientific term that would substantially reduce the amount of one of the components of the formulation and change the coverage of the claims. Nonetheless, Solvay represented that this "correction" would not "alter the substance of the patent in any way that would necessitate reevaluation by an Examiner." The certificate of correction issued some six months later.

43. The formulation patent expires in August 2020. In 2007, Solvay received six months of additional exclusivity from the FDA, until February 2021, based on Solvay's submission of studies relating to the use of the product in a pediatric population.

V. Potential Generic Competition to AndroGel

A. Generic companies challenge Solvay's formulation patent

44. In May 2003, Watson and Paddock each filed an application with the FDA for approval to market a generic version of AndroGel. As part of their applications, Watson and Paddock certified that their generic prod-

ucts did not infringe Solvay's formulation patent and that the patent was invalid.

45. Watson filed its ANDA before Paddock and was therefore eligible for 180-day exclusivity under the Hatch-Waxman Act.

46. Paddock sought a partner to share the costs and risks associated with litigation, together with the rewards from a successful outcome. Paddock eventually reached a deal with Par, which was a top-ten generic drug company and a veteran of pharmaceutical patent litigation. Under the deal, Par agreed to share litigation costs with Paddock, market Paddock's generic product following launch, and share in the resulting profits. Par agreed to partner with Paddock on generic AndroGel only after conducting diligence on Paddock's ANDA in light of Solvay's formulation patent.

47. In August 2003, Solvay and Besins filed separate patent infringement lawsuits against Watson and Paddock, alleging that each infringed the formulation patent. Under the Hatch-Waxman Act, Solvay's lawsuits triggered automatic 30-month stays of final FDA approval of Watson's and Paddock's generic versions of AndroGel. Under FDA rules, the stays expired in January 2006.

B. Solvay prepares for the threat of generic competition

48. In early 2006, under the direction of a new CEO, Solvay analyzed the financial risk from potential generic competition to AndroGel. Solvay concluded that this risk was substantial. As the company's CEO noted at

the time, if generics were to enter, "the economics are obviously not good."

49. Solvay estimated that if generic products were to launch in mid-2006, Solvay would lose about 90 percent of its AndroGel sales within a year. Even factoring in the cost savings to Solvay from not purchasing and promoting AndroGel, Solvay estimated that generic competition would cut its profits by about $125 million a year.

50. Watson projected a similar dramatic impact from generic AndroGel entry. A February 2006 Watson forecast projected that generic AndroGel would sell for about 25 percent of the price of branded AndroGel within a year of generic entry, and that generic products would capture nearly 80 percent of all prescriptions.

51. Par's forecasts projected even steeper price reductions from generic entry. A Par forecast, also prepared in February 2006, projected that the price of generic AndroGel would fall to 15 percent of the branded price within a year and that 90 percent of all prescriptions would go to generic products.

52. In late January 2006, Watson received final FDA approval for its generic product, meaning the FDA had determined that Watson's generic AndroGel was as safe and effective as branded AndroGel. With final FDA approval, Watson could launch its generic version of AndroGel unless Solvay was able to satisfy the relevant burdens to obtain a preliminary injunction in the patent case to prevent Watson's launch.

53. Solvay realized that Watson's receipt of final FDA approval represented a near-term threat to its AndroGel

franchise. Shortly after Watson received FDA approval, Solvay's CEO advised his superiors in Europe that Watson might launch sometime in 2006 even if the patent litigation had not concluded: "The next event will be a court hearing probably in June [2006]. They could then launch if things go well for them."

54. This concern was well-founded. As of February 2006, Watson's forecast for generic AndroGel reflected a generic entry date of January 2007. A February 2006 Par forecast assumed that Watson would launch in March 2006, and Par would follow in September 2006. Par's CEO reported to investment analysts in February 2006 that if generic AndroGel didn't launch in 2006, it "should certainly hit in 2007."

55. Both Watson and Par/Paddock took concrete steps to prepare for a generic launch. Paddock, which had an average annual company-wide equipment budget of about $1 million, spent about $750,000 on commercial manufacturing equipment for generic AndroGel. Watson also ordered commercial manufacturing equipment for generic AndroGel and planned for manufacturing validation in mid-2006 and commercial manufacturing in late 2006.

56. In spite of the threat of generic entry, Solvay did not try to obtain from the court a preliminary injunction to prevent Watson's or Par/Paddock's launch. Rather, Solvay searched for ways to settle its patent disputes and eliminate the near-term threat of generic competition without risking an adverse court decision.

VI. Solvay Pays Watson and Par/Paddock for their Agreement Not to Compete

A. Solvay enters negotiations knowing it will have to compensate Watson and Par/Paddock in exchange for deferred generic competition

57. In preparation for settlement negotiations with Watson and Par, Solvay put together a financial model to analyze its settlement options (hereinafter the "Project Tulip Financial Analysis") (attached as Ex. A). Solvay had already decided that it wanted to defer generic entry until 2015. The 2015 entry date was not based on Solvay's view of the likelihood of prevailing in the patent litigations against its potential generic rivals, but instead was selected for internal business purposes. The purpose of the Project Tulip Financial Analysis was to assess—by evaluating the generics' expected return from continuing to litigate—whether, and under what circumstances, the generic companies would accept this delayed entry date. From the Project Tulip Financial Analysis, Solvay concluded that Watson and Par might agree to a settlement that somewhat deferred generic entry. But if Solvay wanted a settlement that delayed generic entry until 2015, it had to pay Watson and Par.

58. The Project Tulip Financial Analysis also confirmed that Solvay could easily afford to buy Watson's and Par's agreement not to compete. By deferring competition, the parties would preserve monopoly profits that could be shared amongst them—at the expense of the consumer savings that would result from price competition. Thus, even after paying Watson and Par a share of its profits, Solvay still expected to make more

in AndroGel profits by maintaining its monopoly until 2015 than by continuing to litigate.

59. Solvay's Project Tulip Financial Analysis was discussed among the company's CEO and other key executives and formed the basis for Solvay's negotiating strategy. When it negotiated with Watson and Par, Solvay expected that it would need to compensate the generic companies to obtain their agreement not to launch generic AndroGel until 2015.

B. Solvay and Watson agree not to compete but rather to cooperate and share monopoly profits

60. At the beginning of settlement negotiations, Watson proposed that Solvay share AndroGel revenues with Watson through an arrangement under which Watson would co-promote AndroGel to doctors. Just months before, a consulting firm had helped Solvay conduct a comprehensive analysis of Solvay's AndroGel promotion options. That analysis concluded that AndroGel co-promotion was unlikely to make sense for Solvay, and that Watson did not meet the criteria set forth for potential co-promotion partners. Nonetheless, Solvay quickly agreed to consider allocating a portion of AndroGel sales to Watson through a co-promotion arrangement as a means to buy years of protection from competition.

61. Watson was willing to accept Solvay's 2015 generic entry date only if the price was right on the co-promotion arrangement. Watson insisted that it receive a high share of profits from all AndroGel sales to urologists, the group of doctors to which Watson would promote AndroGel. Watson demanded not only a share of

incremental AndroGel sales that Watson might help build, but also a majority share of Solvay's established sales and business. Solvay relented. On April 27, 2006, Solvay's CEO reported to his superiors in Europe that Solvay and Watson had "agreed terms on the Urology 'carve-out' . . . as a basis for settlement of the current litigation."

62. Watson agreed not to market generic AndroGel until 2015 even though it knew of Solvay's plans to introduce a "line extension" product that would eliminate or substantially reduce potential sales of generic AndroGel by 2015. Branded pharmaceutical companies frequently introduce a "line extension," or a new branded product that is related to but different from an existing product, to preserve sales of a branded franchise. This is an effective commercial strategy because generic versions of the existing product are not automatically substitutable for the new "line extension" product.

63. In the case of AndroGel, Solvay plans to market a testosterone gel containing 1.62% testosterone—more than the 1% testosterone contained in AndroGel—that would allow patients to achieve similar therapeutic benefits with less volume of gel. Solvay plans to shift sales from AndroGel to its new low volume product before 2015. Solvay told Watson of its plans for a line extension product during settlement negotiations. Watson accepted Solvay's 2015 generic entry date even though a line extension product could have a severe negative impact on its potential sales of generic AndroGel by 2015. Watson would not have accepted the 2015 generic entry date

in light of these risks, absent Solvay's sharing of AndroGel monopoly profits through the co-promotion deal.

64. Only after Solvay and Watson had agreed to a generic entry date and a "urology carve-out," including the percentage of urology-based profits that Watson would receive, did the parties negotiate other key terms of the co-promotion arrangement, including the number of sales calls Watson would be required to make to doctors.

65. On September 13, 2006, Solvay, Besins, and Watson entered written agreements to settle their patent litigation. Under the parties' settlement, Watson agreed to refrain from marketing generic AndroGel until August 31, 2015, or earlier if another generic company launched a generic version of AndroGel before that date.

66. Solvay and Watson simultaneously entered into the co-promotion deal that provided substantial compensation to Watson. Under the deal, Watson agreed to promote AndroGel to urologists and Solvay agreed to share AndroGel profits with Watson through September 2015. At the time it negotiated the deal, Solvay projected that it would pay Watson about $19 million during the first year of its agreement, rising to over $30 million annually by the end of the deal. Under the parties' arrangement, Watson also obtained the right to co-promote any line extension product, and thus share in any profits of that product.

67. The compensation Solvay agreed to provide Watson was designed to, and did, induce Watson to settle the AndroGel patent litigation by agreeing to refrain from marketing generic AndroGel until 2015. Rather than

compete, Solvay and Watson agreed to cooperate on AndroGel and share in monopoly profits.

68. Solvay and Watson filed a voluntary stipulation of dismissal terminating their patent litigation in the district court. The parties did not file their settlement and co-promotion agreements with the court, nor were the agreements contingent on court approval.

C. Solvay, Par, and Paddock agree not to compete but rather to cooperate and share monopoly profits

69. Under its partnership with Paddock, Par was responsible for conducting the patent litigation with Solvay and negotiating any settlement.

70. Par, like Watson, was willing to settle the AndroGel patent litigation and stay out of the market for the right price. In the words of a senior Par executive, Par was looking to "extract payments" from Solvay in settlement negotiations.

71. During negotiations, Par quickly accepted Solvay's proposed 2015 generic entry date, contingent on the parties' ability to reach agreement on the value that Par would receive in a settlement.

72. To agree on a value, Solvay and Par exchanged forecasts analyzing the profits Par would make from sales of generic AndroGel beginning in 2007. These forecasts discounted Par's generic AndroGel revenues to reflect Par's probability of prevailing in the patent litigation. According to a senior Solvay executive, Solvay developed these forecasts to "demonstrate to [Par] what [its] options are, either litigate or enter into these—this

business arrangement. . . . And if we entered into the business arrangement, we wouldn't be litigating. They go hand in hand."

73. Based on the discounted value of Par's forecasted profits from selling generic AndroGel from 2007 through 2015—which Par would forgo in a settlement—Solvay and Par were able to "agree on a value" Par would receive in exchange for settling the litigation. Solvay and Par agreed on the payments Par would receive for deferring entry before agreeing on the other terms of the deal. On May 13, 2006, the parties confirmed by e-mail their "agreed-upon settlement of $12 million per year for 6 years coupled with manufacturing/development and/or a co-promotion between Par and Solvay."

74. About two weeks after Solvay agreed to pay Par $12 million per year for six years, the parties met to discuss what type of business arrangement would accompany the settlement. The parties considered a number of options, including co-promoting various Solvay drugs; manufacturing AndroGel or serving as a back-up manufacturer; and assisting in development of new AndroGel formulations. Ultimately, the parties decided that Par would co-promote AndroGel to doctors and receive $10 million annually, and Paddock would serve as a back-up manufacturer for AndroGel and receive $2 million annually. As a Besins executive stated in an e-mail, a "back-up manufacturer strategy [was] a partial way to compensate Parr [sic] for not entering the market."

75. After Solvay and Par had agreed to the 2015 generic entry date and $12 million per year in payments, and settled on the concept of AndroGel co-promotion,

the parties negotiated other key terms of the co-promotion arrangement. In an initial term sheet, Solvay proposed that Par perform at least 90,000 sales calls a year and promote AndroGel first in each call. Under this proposal, Solvay would have paid Par about $110 per sales call, about the same amount Solvay had received in another co-promotion arrangement it had entered. Solvay ultimately agreed, however, to accept substantially fewer sales calls—only 30,800—and Par did not even commit to promoting AndroGel in the first position. Under the final agreement, Solvay agreed to pay Par over $300 per sales call.

76. On September 13, 2006, the same day the Solvay/Watson agreements were signed, Solvay, Besins, Par, and Paddock entered written agreements to settle their patent litigation. Under the parties' settlement, Par and Paddock agreed to refrain from marketing generic AndroGel until August 31, 2015, or earlier if another generic company launched a generic version of AndroGel before that date.

77. Solvay and Par simultaneously entered into co-promotion and back-up manufacturing deals which provided substantial compensation to Par and Paddock. Under the co-promotion deal, Solvay agreed to pay Par $10 million per year for six years and Par agreed to promote AndroGel to primary care doctors. Under the back-up manufacturing deal, which Par signed but assigned to Paddock, Solvay agreed to pay Paddock $2 million per year for six years and Paddock agreed to serve as a back-up manufacturer for AndroGel. Solvay also agreed to reimburse Paddock for any capital expendi-

tures associated with meeting FDA requirements to manufacture AndroGel.

78. At the same time Par signed its agreements with Solvay, it agreed to pay $6 million up front to Paddock, which was accomplished by transferring title of Paddock's ANDA to Par. This payment was necessary to obtain Paddock's assent to the patent settlement.

79. The compensation Solvay agreed to provide Par and Paddock was designed to, and did, induce Par and Paddock to settle the AndroGel patent litigation by agreeing to refrain from marketing generic AndroGel until 2015. Rather than compete, Solvay, Par and Paddock agreed to cooperate on AndroGel and share in monopoly profits.

80. The district court hearing the patent litigation dismissed Solvay's patent lawsuit against Paddock under a consent judgment filed by the parties. The parties did not file their settlement, co-promotion, and back-up manufacturing agreements with the court, nor were the agreements contingent on court approval.

D. Solvay's business deals with Watson and Par/Paddock make economic sense only as payments to defer generic entry

81. The co-promotion and back-up manufacturing deals induced Watson, Par, and Paddock to agree to refrain from marketing generic AndroGel until 2015 and provided Solvay the means to share preserved AndroGel monopoly profits with its potential competitors.

82. Solvay's co-promotion deals with Watson and Par are not independent business transactions, for at least the following reasons:

- Prior to settlement discussions with Watson and Par, Solvay had not been looking for a co-promotion partner. Its 2006 business plan for AndroGel assumed "no co-promotion during plan period"; two prior AndroGel co-promotion efforts had been canceled because they had "no significant impact" on sales trends; and a late 2005 analysis from a consulting firm had concluded that future AndroGel co-promotion offered "little revenue upside."

- Solvay's payments to Watson and Par far exceed the value of the services provided. Solvay projected that it would pay Watson more than $19 million annually, or over $300 per sales call. Solvay agreed to pay Par $10 million per year, also over $300 per sales call. By contrast, Solvay had previously entered an AndroGel co-promotion deal involving projected payments of around $30-$45 per sales call. A senior Watson executive has stated that even $150 per call would be a "ridiculous" rate—and yet Watson and Par are receiving more than twice that rate from Solvay.

- Other terms of the co-promotion deals also depart from industry standards. Among other things, unlike Solvay's previous AndroGel co-promotion agreements, Solvay cannot terminate either deal early if co-promotion does not improve AndroGel sales.

- Before agreeing to the co-promotion deals, Solvay did not analyze how the Watson or Par co-promotion efforts would affect AndroGel sales—as it did before entering into earlier AndroGel co-promotion agreements.

- When it entered the co-promotion deals, Solvay examined the "Estimated Impact of Settlement" on Solvay's budget and accounted for co-promotion as a cost of settlement rather than a profitable business deal.

83. Solvay was willing to enter into the co-promotion deals only because Watson and Par agreed to refrain from competing with generic AndroGel until 2015.

84. Solvay's back-up manufacturing deal with Paddock is not an independent business transaction, for at least the following reasons:

- The back-up manufacturing deal guarantees Paddock $2 million per year for six years, regardless of whether Paddock ever manufactures AndroGel or ever becomes FDA-qualified to manufacture AndroGel.

- Before settlement discussions with Par, Solvay had considered and rejected several options for AndroGel back-up manufacturing. Solvay had concluded that the $10-12 million in capital expenditures required to qualify a back-up manufacturer could not be justified in light of the reliable source of supply from Besins.

- Before entering the back-up manufacturing deal, Solvay conducted no diligence on Paddock's manufacturing facilities. A later site visit showed that Paddock was not able to manufacture AndroGel using Besins' already-FDA-approved process, requiring substantial and lengthy efforts to conform Paddock's facilities and processes to meet FDA-approved standards. Solvay has paid Paddock $2 million per year since September 2006 despite the fact that Solvay did not even apply for the required FDA approval for Paddock to serve as a back-up manufacturer until November 2008. Under the parties' deal, Solvay must also reimburse Paddock for any capital expenditures in connection with its qualification efforts.

85. Solvay was willing to enter into the back-up manufacturing deal only because Par and Paddock agreed to refrain from competing with generic AndroGel until 2015.

VII. Solvay's Patent Was Unlikely to Prevent Generic Competition to AndroGel

86. Over the course of their patent litigation with Solvay and Besins, Watson and Par/Paddock developed persuasive arguments and amassed substantial evidence that their generic products did not infringe the formulation patent and that the patent was invalid and/or unenforceable. As a result, Solvay was not likely to prevail in each of its patent lawsuits to prevent competition to AndroGel.

87. Watson and Par/Paddock argued that the scope of the formulation patent was limited, and that their products were outside the scope of the patent claims. They assembled evidence that their generic products did not infringe the patent because their products contained ingredients that the patent did not cover, or amounts of ingredients outside the amounts covered by the patent.

88. Watson and Par/Paddock also argued that the formulation patent was invalid. Among other things, these firms developed evidence that:

- The patent was invalid under 35 U.S.C. § 102(b) for prior commercial sale or public use of the patented invention, in that Besins offered the invention for sale to Solvay in 1995—a fact that Solvay and Besins withheld from the Patent and Trademark Office.
- The patent was invalid as obvious under 35 U.S.C. § 103 because the gel formulations and related methods covered by the patent were obvious variations of existing products and methods. As a Paddock executive noted in a 2006 e-mail characterizing the views of Paddock's CEO, Paddock was "providing [testosterone] gel formulations to customers over 10 years ago, so the patent simply cannot be valid."
- Many of the patent claims were invalid under 35 U.S.C. § 112 for failure to meet the "written description" requirement.

89. The generic firms also argued that the certificate of correction, which changed the scope of some of the patent claims, was invalid and, because the certificate of correction issued after Solvay filed its patent suits, the certificate did not apply to the pending litigations. Watson further argued that the patent was unenforceable based on evidence that Solvay and Besins did not disclose their 1995 commercial supply agreement to the patent examiner when they applied for the formulation patent.

90. By late 2005, Watson and Par/Paddock had filed motions for summary judgment on two of these issues, and addressed others in claim construction briefing and expert reports.

91. Solvay and Besins bore the burden of proving that Watson and Par/Paddock each infringed the formulation patent—in other words, that the generic products were within the scope of the patent claims. Solvay and Besins had not met their burden when the litigation ended in settlements.

92. Solvay and Besins were unlikely to prevent generic entry through their patent lawsuits. To do so, Solvay and Besins had to prove infringement by both Watson and Par/Paddock, and also had to defeat each of the generics' invalidity and unenforceability arguments. If either Watson or Par/Paddock had prevailed on any one of these issues, Solvay's formulation patent could not have blocked generic entry, and consumers would have saved millions of dollars a year.

VIII. The AndroGel Settlements Harm Competition and Consumer Welfare

93. Prior to their settlement, Solvay and Watson were potential competitors. By entering into their agreement, Solvay and Watson eliminated the potential that (1) Watson would have entered "at risk" and marketed generic AndroGel before a final appellate decision in the AndroGel patent litigation; (2) Watson would have prevailed in the patent litigation and marketed generic AndroGel after the litigation but well before 2015; or (3) Solvay and Watson would have agreed to settle their patent litigation on terms that did not compensate Watson, but provided for generic entry earlier than 2015.

94. Prior to their settlement, Solvay and Par/Paddock were potential competitors. By entering into their agreement, Solvay and Par/Paddock eliminated the potential that (1) Par/Paddock would have entered "at risk" and marketed generic AndroGel before a final appellate decision in the AndroGel patent litigation; (2) Par/Paddock would have prevailed in the patent litigation and marketed generic AndroGel after the litigation but well before 2015; or (3) Solvay and Par/Paddock would have agreed to settle their patent litigation on terms that did not compensate Par/Paddock, but provided for generic entry earlier than 2015.

95. If Solvay had settled with Watson only, Par had ample financial incentive to continue to challenge Solvay's patent. During settlement negotiations with Solvay, Par prepared forecasts that showed the risk to Solvay if it settled with Watson and not with Par—that risk being that Par would continue to litigate and prevail.

Par's forecasts also showed that, even as a generic applicant entering six months after Watson, Par expected to earn significantly more in generic AndroGel profits than its expected costs of litigation.

96. Defendants eliminated this potential competition and harmed consumers by entering agreements that compensated Watson and Par/Paddock for agreeing to refrain from marketing generic AndroGel until 2015. Defendants' agreements to eliminate potential competition until 2015 were based not on the strength of Solvay's patent, but on the compensation Solvay provided to Watson, Par, and Paddock in exchange for a 2015 generic entry date. Absent compensation, Watson and Par/Paddock would not have agreed to refrain from competing until 2015.

97. Moreover, absent the compensation Solvay agreed to provide, generic competition to AndroGel would have occurred before 2015 because (1) Watson and/or Par/Paddock would have marketed generic AndroGel before a final appellate decision in the AndroGel patent litigation; (2) Solvay would not have prevailed against each of Watson and Par/Paddock in the patent litigation; or (3) Solvay would have agreed to settle the patent litigation on terms that did not compensate Watson and Par/Paddock, but provided for generic entry earlier than 2015.

98. Entry of generic AndroGel would give consumers the choice between branded AndroGel and lower-priced generic versions of AndroGel. Many consumers would choose to purchase lower-priced, generic drugs instead of higher-priced, branded AndroGel. Entry of generic

versions of AndroGel would quickly and significantly reduce Solvay's sales of AndroGel, promote economic efficiency, and lead to a significant reduction in the average price purchasers pay for AndroGel and its generic equivalents. Consumers would save hundreds of millions of dollars a year by purchasing generic versions of AndroGel. Through their anticompetitive agreements, Defendants have retained those potential consumer savings for themselves.

99. The ability to launch generic versions of AndroGel in 2015 will likely provide little benefit to consumers because Solvay plans to switch sales from AndroGel to its new branded product, a low volume version of AndroGel, well before 2015. Generic AndroGel would not be automatically substitutable for Solvay's new branded product. Moreover, Solvay has even considered pulling AndroGel from the market before generics enter in 2015, which would likely eliminate altogether the market for generic AndroGel.

100. The Hatch-Waxman Act was designed to promote generic competition while preserving incentives for branded innovation. Exclusion payment settlements, including Defendants', distort the careful balance achieved by the Hatch-Waxman Act by eliminating generic companies' incentives to compete.

101. Exclusion payments are not a natural by-product of incentives created by the Hatch-Waxman Act. Rather, pharmaceutical patent litigation can be, and often is, resolved without exclusion payments from branded companies to generic companies. For instance, in fiscal year 2004, following FTC enforcement actions chal-

lenging exclusion payments, 14 pharmaceutical patent settlements were filed with the FTC under the Medicare Modernization Act and none involved an exclusion payment.

102. Through its exclusion payment settlements, Solvay bought protection from competition not contemplated by the Hatch-Waxman Act—with consumers paying the price for its anticompetitive conduct.

IX. Solvay's Market and Monopoly Power

103. Solvay has exercised and continues to exercise market and monopoly power in the United States with respect to AndroGel. Direct evidence of this power includes Solvay's ongoing ability to price AndroGel substantially higher than the projected price of competing generic versions of AndroGel and to exclude potential competitors by providing significant compensation to forestall entry.

104. In addition, Solvay's market and monopoly power can be shown through circumstantial evidence, including a high share of a relevant market with substantial barriers to entry. Empirical and documentary evidence demonstrate that the relevant market for antitrust purposes in this case is no broader than testosterone drugs delivered transdermally (through the skin) and approved by the FDA for sale in the United States. Other testosterone drugs, such as those delivered by injection, are not close enough substitutes to prevent Solvay and other market participants from profitably raising prices. AndroGel has consistently accounted for more than 70 percent of transdermal testosterone drug sales. Sub-

stantial barriers to entry exist in the transdermal testosterone drug market, including the need to conduct expensive clinical trials and obtain FDA approval.

105. Narrower relevant product markets may also exist for purposes of assessing Defendants' conduct and Solvay's market and monopoly power, including one consisting of AndroGel and its generic equivalents. A unique competitive relationship exists between branded drugs and their generic equivalents, including AndroGel and generic AndroGel. Although other testosterone drugs may be used to treat low testosterone, the availability of these drugs is not sufficient to prevent the anticompetitive effects from Defendants' conduct. Solvay has consistently held a 100 percent share of sales of AndroGel and its generic equivalents. Possible sellers of generic AndroGel face substantial barriers to entry, including the need to obtain FDA approval, costly specialized equipment and facilities, and Solvay's ability to trigger an automatic 30-month stay of FDA approval by filing a patent infringement lawsuit. Moreover, Defendants' agreements have diminished the economic incentives to potential generic entrants of challenging the AndroGel formulation patent, since the terms of the agreements allow for immediate entry of generic AndroGel by Watson and Par/Paddock upon the launch of generic AndroGel by any other generic manufacturer.

Count I

Restraint of Trade—Against Watson and Solvay

106. Plaintiffs reallege and incorporate by reference the allegations in all of the paragraphs above. The

agreement between Watson and Solvay that Watson will not compete by marketing a generic version of AndroGel until 2015, in exchange for compensation, is an unfair method of competition that violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

Count II

Restraint of Trade—Against Par, Paddock, and Solvay

107. Plaintiffs reallege and incorporate by reference the allegations in all of the paragraphs above.

108. The agreement among Par, Paddock, and Solvay that Par/Paddock will not compete by marketing a generic version of AndroGel until 2015, in exchange for compensation, is an unfair method of competition that violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

Count III

Monopolization—Against Solvay

109. Plaintiffs reallege and incorporate by reference the allegations in all of the paragraphs above.

110. At all times relevant to this complaint, Solvay has had monopoly power in the United States with respect to AndroGel.

111. Solvay has willfully maintained its monopoly power through its agreements with Watson, Par, and Paddock that those companies will not compete by marketing generic versions of AndroGel until 2015, in exchange for compensation. Entry of a generic version of AndroGel would eliminate Solvay's monopoly with respect to AndroGel. At the time of the agreements, Wat-

son and Par/Paddock were threats to enter with generic versions of AndroGel before 2015. Eliminating this threat of generic entry is conduct that is reasonably capable of contributing significantly to Solvay's continued monopoly power. Solvay has willfully maintained its monopoly and excluded competition through its anticompetitive conduct. Solvay has unlawfully extended its monopoly not on the strength of its patent, but rather by compensating its potential competitors.

112. Solvay's acts are anticompetitive and constitute an unfair method of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

Prayer for Relief

WHEREFORE, Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), empowers this Court to issue a permanent injunction against violations of the FTC Act and, in the exercise of its equitable jurisdiction, to order ancillary equitable relief to remedy the injury caused by Defendants' violations; therefore, the FTC requests that this Court, as authorized by 15 U.S.C. § 53(b), 15 U.S.C. § 26 and its own equitable powers, enter final judgment against Defendants on Counts I-III, declaring, ordering, and adjudging:

1. That the agreement between Watson and Solvay violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a);

2. That the agreement among Par, Paddock, and Solvay violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a);

3. That Solvay's course of conduct, including its agreements with Watson, Par, and Paddock, violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a);

4. That Defendants are permanently enjoined from engaging in similar and related conduct in the future; and

5. That the Court grant such other equitable relief as the Court finds necessary to redress and prevent recurrence of Defendants' violations of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), as alleged herein.

Dated: May 28, 2009

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Respectfully submitted,

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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
(Atlanta)

Civil Docket For Case No. 1:03-cv-02501-TWT

UNIMED PHARMACEUT, ET. AL.

v.

WATSON PHARMA[CEUTICALS, INC.]

DOCKET ENTRIES

DATE	DOCKET NUMBER	PROCEEDINGS
8/21/03	1	COMPLAINT filed and summons(es) issued. Consent form to proceed before U.S. magistrate and pretrial instructions given to attorney; jury demand FILING FEE $ 150.00 RECEIPT # 509983 (jdb) (Entered: 08/25/2003)
		* * * * *
8/21/03	3	AMENDED COMPLAINT by plaintiff Unimed Pharmaceut adding Laboratories Besins; jury demand (jdb) (Entered: 08/25/2003)
		* * * * *

DATE	DOCKET NUMBER	PROCEEDINGS
10/27/03	8	ANSWER by Watson Pharma to first amended complaint [3-1] and COUNTERCLAIM against Unimed Pharmaceut, Laboratories Besins Discovery ends 7/23/04 (dr) (Entered: 10/29/2003)
		* * * * *
11/17/03	10	ANSWER by Unimed Pharmaceut to counterclaim [8-2]; jury demand. (dr) (Entered: 11/21/2003)
		* * * * *
2/26/04	22	HEARING HELD before Judge Thomas W. Thrash to resolve scheduling issues; Court is allowing plas 15 depositions to be taken for both cases and each dft 12 depositions extending time limits from 7 hours to 10 hours each; Mr. Ladow to prepare order (dr) (Entered: 03/03/2004)
		* * * * *
7/12/04	40	Minute Entry for Telephone Conference regarding electronic discov-

DATE	DOCKET NUMBER	PROCEEDINGS
		ery dispute held on 7/12/2004 before Judge Thomas W. Thrash Jr.; Court directed filing of letters from counsel regarding disputes; Court set forth limitations as to electronic discovery as detailed on the record as accepted in Exhibit A &B. (Exhibits attached to minute entry in case 03-cv-2503-TWT) (Court Reporter Darla Coulter.) (dr) (Entered: 07/21/2004)
		* * * * *
10/5/04	46	NOTICE of Hearing: In Chambers telephone Conference set for 10/21/2004 10:00 AM before Judge Thomas W. Thrash Jr. on discovery dispute. (ss) (Entered: 10/05/2004)
		* * * * *
10/15/04	49	NOTICE of Hearing: In Chambers Conference by telephone set for 10/21/2004 10:00 AM before Judge Thomas W. Thrash Jr., amended to include further discovery disputes. (ss) (Entered: 10/15/2004)

DATE	DOCKET NUMBER	PROCEEDINGS
		* * * * *
10/21/04	52	Minute Entry for proceedings held before Judge Thomas W. Thrash Jr.: In Chambers Conference held on 10/21/2004; Court heard from counsel re discovery; counsel advised issues in latter by Mr. Rabin have been resolved; Court DENIES the motion to compel; Mr. Taylor to prepare order summarizing Court's rulings. (Court Reporter Darla Coulter.) (dr) (Entered: 10/28/2004)
		* * * * *
7/25/05	89	First Claim Construction Brief *of Watson Pharmaceuticals, Inc.* (Rabin, David) (Entered: 07/25/2005)
		* * * * *
7/25/05	91	FILED UNDER SEAL First Markman Brief *of Unimed Pharmaceuticals, Inc. and Laboratories Besins Iscovesco.* (Attachments: # 1 Exhibit Exhibit A (Part 1)# 2 Exhibit Exhibit A (Part 2)# 3 Ex-

DATE	DOCKET NUMBER	PROCEEDINGS
		hibit Exhibit B# 4 Exhibit Exhibit C# 5 Exhibit Exhibit D# 6 Exhibit Exhibit E# 7 Exhibit Exhibit F# 8 Exhibit Exhibit G# 9 Exhibit Exhibit H# 10 Exhibit Exhibit I (Part 1) # 11 Exhibit Exhibit I (Part 2) # 12 Exhibit Exhibit I (Part 3)# 13 Exhibit Exhibit I (Part 4)# 14 Exhibit Exhibit J# 15 Exhibit Exhibit K# 16 Exhibit Exhibit L# 17 Exhibit Exhibit M# 18 Exhibit Exhibit N# 19 Exhibit Exhibit O) (Ferguson, James) Modified on 7/28/2005 to restrict access as pleading inadvertently contained sealed material—attorney advised to file motion to seal pleading w/in 24 hours—chambers contacted (fmm). Modified on 8/3/2005 (dr). (Entered: 07/25/2005)
		* * * * *
8/12/05	106	RESPONSE re 91 Markman Brief,,, filed by Watson Pharmaceuticals, Inc.. (Attachments: # 1 Appendix Appendix Exhibits 38-42) (Rabin, David) (Entered: 08/12/2005)

DATE	DOCKET NUMBER	PROCEEDINGS
8/12/05	107	Second Claim Construction Brief filed by Unimed Pharmaceuticals, Inc., Laboratories Besins Iscovesco.. (Attachments: # 1 Exhibit Cover and Index# 2 Exhibit P-S# 3 Exhibit T (Pages 1-11) # 4 Exhibit T (Pages 12-22)# 5 Exhibit U-V# 6 Exhibit W# 7 Exhibit X-DD# 8 Exhibit EE) (Ferguson, James) (Entered: 08/12/2005)
		* * * * *
9/9/05	117	MOTION for Partial Summary Judgment with Brief In Support by Watson Pharmaceuticals, Inc.. (Attachments: # 1 Brief # 2 Statement of Material Facts) (Rabin, David)—Please refer to http://www.gand.uscourts.gov to obtain the Notice to Respond to Summary Judgment Motion form contained on the Court's website.—(Entered: 09/09/2005)
		* * * * *
10/17/05	122	Consolidated Memorandum in Opposition re 117 MOTION for Partial

DATE	DOCKET NUMBER	PROCEEDINGS
		Summary Judgment filed by Unimed Pharmaceuticals, Inc., Laboratories Besins Iscovesco. (Attachments: # 1 Exhibit A.1# 2 Exhibit A (part 2)# 3 Exhibit A (part 3)# 4 Exhibit B# 5 Exhibit C# 6 Exhibit D# 7 Exhibit E# 8 Exhibit F# 9 Exhibit G# 10 Exhibit H# 11 Exhibit I (part 1)# 12 Exhibit I (part 2)# 13 Exhibit I (part 3)# 14 Exhibit I (part 4)# 15 Exhibit J# 16 Exhibit K# 17 Exhibit L (part 1)# 18 Exhibit L (part 2)# 19 Exhibit M# 20 Exhibit N# 21 Exhibit O# 22 Exhibit P# 23 Exhibit Q# 24 Exhibit R# 25 Exhibit S# 26 Exhibit T# 27 Exhibit U# 28 Exhibit V (part 1)# 29 Exhibit V (part 2)# 30 Exhibit W# 31 Exhibit X (part 1)# 32 Exhibit X (part 2)# 33 Exhibit Y# 34 Exhibit Z# 35 Exhibit AA# 36 Exhibit BB) (Ferguson, James) Modified text on 10/18/2005 (dr). (Entered: 10/17/2005)
10/17/05	123	STATEMENT re 122 Response in Opposition to Motion,,, filed by Unimed Pharmaceuticals, Inc.,

DATE	DOCKET NUMBER	PROCEEDINGS
		Laboratories Besins Iscovesco. (Ferguson, James) (Entered: 10/17/2005)
10/17/05	124	Response to Statement of Material Facts re 117 MOTION for Partial Summary Judgment filed by Unimed Pharmaceuticals, Inc., Laboratories Besins Iscovesco. (Ferguson, James) (Entered: 10/17/2005)
		* * * * *
11/11/05	139	RESPONSE to 123 Statement *of additional facts which are material and present a genuine issue for trial by plaintiffs* filed by Watson Pharmaceuticals, Inc.. (Rabin, David) Modified text on 11/14/2005 (dr). (Entered: 11/11/2005)
11/11/05	140	REPLY to plaintiff's consolidated opposition to 117 MOTION for Partial Summary Judgment filed by Watson Pharmaceuticals, Inc. (Rabin, David) Modified text on 11/14/2005 (dr). (Entered: 11/11/2005)

DATE	DOCKET NUMBER	PROCEEDINGS

* * * * *

11/23/05	144	MOTION for Partial Summary Judgment *of Invalidity of Claims 1-30 for Failure to Comply with the Written-Description Requirement* with Brief In Support by Watson Pharmaceuticals, Inc.. (Attachments: # 1 Memorandum of Law in Support# 2 Statement of Material Facts as to Which There are No Genuine Issues to be Tried) (Rabin, David)—Please refer to http://www.gand.uscourts.gov to obtain the Notice to Respond to Summary Judgment Motion form contained on the Court's website.—(Entered: 11/23/2005)

* * * * *

12/19/05	151	RESPONSE in Opposition re 144 MOTION for Partial Summary Judgment *of Invalidity of Claims 1-30 for Failure to Comply with the Written-Description Requirement* filed by Unimed Pharmaceuticals, Inc., Laboratories Besins Isco-

DATE	DOCKET NUMBER	PROCEEDINGS
		vesco. (Attachments: # 1 Exhibit CC# 2 Exhibit DD# 3 Exhibit EE# 4 Exhibit FF# 5 Exhibit GG# 6 Exhibit HH# 7 Exhibit II# 8 Exhibit JJ# 9 Exhibit KK) (Ferguson, James) (Entered: 12/19/2005)
12/19/05	152	STATEMENT re 151 Response in Opposition to Motion, filed by Unimed Pharmaceuticals, Inc., Laboratories Besins Iscovesco. (Ferguson, James) (Entered: 12/19/2005)
12/19/05	153	Response to Statement of Material Facts re 144 MOTION for Partial Summary Judgment *of Invalidity of Claims 1-30 for Failure to Comply with the Written-Description Requirement* filed by Unimed Pharmaceuticals, Inc., Laboratories Besins Iscovesco. (Ferguson, James) (Entered: 12/19/2005)
		* * * * *
1/19/06	164	REPLY Memorandum of Law in Support its 144 MOTION for Partial Summary Judgment *of In-*

DATE	DOCKET NUMBER	PROCEEDINGS
		validity of Claims 1-30 for Failure to Comply with the Written-Description Requirement filed by Watson Pharmaceuticals, Inc.. (Attachments: # 1 Exhibit 48# 2 Exhibit 49# 3 Exhibit 50# 4 Exhibit 51# 5 Exhibit 52# 6 Exhibit 53) (Rabin, David) (Entered: 01/19/2006)
1/19/06	165	RESPONSE re 123 Statement *of Additional Facts Which Are Material and Present a Genuine Issue for Trial* filed by Watson Pharmaceuticals, Inc.. (Rabin, David) (Entered: 01/19/2006)
		* * * * *
5/17/06		Minute Entry for proceedings held before Judge Thomas W. Thrash Jr.: In Chambers Telephone Conference held on 5/17/2006. (At direction of Court this is only entry) (Court Reporter Darla Coulter.) (ss) (Entered: 05/17/2006)
6/1/06		Minute Entry for proceedings held before Judge Thomas W. Thrash

DATE	DOCKET NUMBER	PROCEEDINGS
		Jr.: Telephone Conference held on 6/1/2006. (No PDF attached) (Court Reporter Darla Coulter.) (ss) (Entered: 06/05/2006)
7/5/06		Minute Entry for proceedings held before Judge Thomas W. Thrash Jr.: Status Conference held on 7/5/2006. No PDF attached. (Court Reporter Andy Ashley.) (ss) (Entered: 07/05/2006)
7/31/06		Minute Entry for proceedings held before Judge Thomas W. Thrash Jr.: Status Conference held on 7/31/2006. Proceedings ORDERED UNDER SEAL. No PDF attached. (Court Reporter Elise Evans.) (ss) (Entered: 07/31/2006)
8/1/06	170	NOTICE of TELECONFERENCE Hearing: Status Conference set for 9/6/2006 02:15 PM before Judge Thomas W. Thrash Jr., plaintiff counsel to originate call. (ss) (Entered: 08/01/2006)
9/6/06	171	NOTICE of TELECONFERENCE Hearing: Status Confer-

DATE	DOCKET NUMBER	PROCEEDINGS
		ence set for 9/13/2006 02:15 PM before Judge Thomas W. Thrash Jr.. (ss) (Entered: 09/06/2006)
9/6/06	172	FILED UNDER SEAL—Minute Entry for proceedings held before Judge Thomas W. Thrash Jr.: Telephone Conference held on 9/6/2006. (Court Reporter Pat Tanner.) (dr) Additional attachment(s) added/verified by cdg on 9/7/2006 (dr). (Entered: 09/07/2006)
9/13/06	173	FILED UNDER SEAL—Minute Entry for proceedings held before Judge Thomas W. Thrash Jr.: Telephone Conference held on 9/13/2006. (Court Reporter Andy Ashley.) (dr) Additional attachment(s) added/verified by cdg on 9/13/2006 (dr). (Entered: 09/13/2006)
9/14/06	174	STIPULATION of Dismissal by Unimed Pharmaceuticals, Inc., Watson Pharmaceuticals, Inc., Laboratories Besins Iscovesco. (Grout, Bradley) (Entered: 09/14/2006)

DATE	DOCKET NUMBER	PROCEEDINGS
9/15/06		Clerk's Entry of Dismissal re: 174 Stipulation of Dismissal (dr) (Entered: 09/15/2006)

* * * * *

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
(Atlanta)

Civil Docket for Case # 1:03-cv-02503-TWT

UNIMED PHARMACEUT, ET. AL.

v.

PADDOCK LABORATORIES

DOCKET ENTRIES

DATE	DOCKET NUMBER	PROCEEDINGS
8/21/03	1	COMPLAINT filed and summons(es) issued. Consent form to proceed before U.S. magistrate and pretrial instructions given to attorney; jury demand FILING FEE $ 150.00 RECEIPT # 509983 (jdb) (Entered: 08/25/2003)
	* * * * *	
8/22/03	4	AMENDED COMPLAINT by plaintiff adding Laboratories Besins; jury demand (jdb) (Entered: 08/25/2003)
	* * * * *	

DATE	DOCKET NUMBER	PROCEEDINGS
10/2/03	11	ORDER by Judge Richard W. Story, that the Clerk is DIRECTED to reassign case to Judge Thomas W. Thrash. (cc) (lme) (Entered: 10/03/2003)
		* * * * *
10/22/03	14	ANSWER by Paddock Laboratories to complaint [4-1] and COUNTERCLAIM against Unimed Pharmaceut, Laboratories Besins Discovery ends 7/18/04, 11/11/03 for Unimed Pharmaceut (dr) (Entered: 10/24/2003)
11/12/03	15	ANSWER by Unimed Pharmaceut to counterclaim [14-2]; jury demand. (dr) (Entered: 11/19/2003)
		* * * * *

DATE	DOCKET NUMBER	PROCEEDINGS
2/24/04	26	HEARING HELD before Judge Thomas W. Thrash to resolve scheduling issues; Court is allowing plas 15 depositions to be taken for both cases and each dft 12 depositions extending time limits from 7 hours to 10 hours each; Mr. Ladow to prepare order (dr) (Entered: 03/03/2004)
		* * * * *
7/12/04	32	Minute Entry for Telephone Conference regarding electronic discovery dispute held on 7/12/2004 before Judge Thomas W. Thrash Jr.; Court directed filing of letters from counsel regarding disputes; Court set forth limitations as to electronic discovery as detailed on the record as accepted in Exhibit A &B; (Attachments: # 1 Attachment 1# 2 Attachment 1 Exhibit A# 3 Attachment 1 Exhibit B# 4 Attachment 2# 5 Attachment 2 Exhibit 1# 6 Attachment 2 Exh 2# 7 Attachment 2 Exh 3# 8 Attachment 2 Exh 4# 9 Attachment 2 Exh 5# 10 Attachment 2 Exh 6# 11 Attach-

DATE	DOCKET NUMBER	PROCEEDINGS
		ment 2 Exh 7# 12 Attachment 2 Exh 8# 13 Attachment 2 Exh 9# 14 Attachment 2 Exh 10# 15 Attachment 2 Exh 11# 16 Attachment 2 Exh 12# 17 Attachment 2 Exh 13# 18 Attachment 2 Exh 14# 19 Attachment 2 Exh 15# 20 Attachment 2 Exh 16# 21 Attachment 2 Exh 17# 22 Attachment 2 Exh 18) (Court Reporter Darla Coulter.) (dr) (Entered: 07/21/2004)
		* * * * *
10/5/04	37	NOTICE of Hearing: In Chambers telephone Conference set for 10/21/2004 10:00 AM before Judge Thomas W. Thrash Jr. on discovery dispute. (ss) (Entered: 10/05/2004)
10/15/04	38	NOTICE of Hearing: In Chambers Conference by telephone set for 10/21/2004 10:00 AM before Judge Thomas W. Thrash Jr., amended to include further discovery disputes. (ss) (Entered: 10/15/2004)
10/21/04	39	Minute Entry for proceedings held before Judge Thomas W. Thrash Jr.: In Chambers Conference held

DATE	DOCKET NUMBER	PROCEEDINGS
		on 10/21/2004; Court heard from counsel re discovery; counsel advised issues in latter by Mr. Rabin have been resolved; Court DENIES the motion to compel; Mr. Taylor to prepare order summarizing Court's rulings. (Court Reporter Darla Coulter.) (dr) (Entered: 10/28/2004)
		* * * * *
7/25/05	59	FILED UNDER SEAL First Claim Construction Brief by Paddock Laboratories. (Attachments: # 1 # 2 # 3 # 4 # 5 # 6 # 7 # 8 # 9 # 10 # 11) (Trigg, Mark) Modified on 7/27/2005 to restrict access as pleading inadvertently contained sealed material—attorney advised to file motion to seal pleading w/in 24 hours—chambers contacted. (fmm). Modified on 8/3/2005 (dr). (Entered: 07/25/2005)
7/25/05	60	FILED UNDER SEAL First Markman Brief *Unimed Pharmaceuticals, Inc. and Laboratories Besins Iscovesco.* (Attachments: # 1 Exhibit A (Part 1)# 2 Exhibit A (Part

DATE	DOCKET NUMBER	PROCEEDINGS
		2)# 3 Exhibit B# 4 Exhibit C# 5 Exhibit D# 6 Exhibit E# 7 Exhibit F# 8 Exhibit G# 9 Exhibit H# 10 Exhibit I (Part 1)# 11 Exhibit I (Part 2)# 12 Exhibit I (Part 3)# 13 Exhibit Part I (Part 4)# 14 Exhibit J# 15 Exhibit K# 16 Exhibit L# 17 Exhibit M# 18 Exhibit N# 19 Exhibit O) (Ferguson, James) Modified on 7/28/2005 to restrict access as pleading inadvertently contained sealed material—attorney advised to file motion to seal pleading w/in 24 hours—chambers contacted. (fmm). Modified on 8/3/2005 (dr). (Entered: 07/25/2005)
		* * * * *
8/12/05	70	Second Claim Construction Brief filed by Paddock Laboratories, Inc... (Attachments: # 1 # 2) (Trigg, Mark) (Entered: 08/12/2005)
8/12/05	71	Second Claim Construction Brief filed by Unimed Pharmaceuticals, Inc., Laboratories Besins Iscovesco.. (Attachments: # 1 Exhibit Cover and Index# 2 Exhibit P-S# 3

DATE	DOCKET NUMBER	PROCEEDINGS
		Exhibit T (Pages 1-11)# 4 Exhibit T (Pages 12-22)# 5 Exhibit U-V# 6 Exhibit W# 7 Exhibit X-DD# 8 Exhibit EE) (Ferguson, James) (Entered: 08/12/2005)
		* * * * *
8/26/05	78	NOTICE by Unimed Pharmaceuticals, Inc., Laboratories Besins Iscovesco re 71 Claim Construction Brief, *Supplemental Pleading Regarding Claim Construction* (Attachments: # 1 Exhibit A) (Ferguson, James) (Entered: 08/26/2005)
		* * * * *
9/27/05	80	MOTION for Partial Summary Judgment with Brief In Support by Paddock Laboratories, Inc.. (Attachments: # 1 Brief Memorandum of Law in Support of its Motion for Partial Summary Judgment as to the Inapplicability and Invalidity of the Certificate of Correction # 2 Statement of Material Facts) (Trigg, Mark)—Please refer to http://www.gand.uscourts.gov to obtain the Notice to Respond to

DATE	DOCKET NUMBER	PROCEEDINGS
		Summary Judgment Motion form contained on the Court's website.— (Entered: 09/27/2005)
10/17/05	81	Consolidated Memorandum in Opposition re 80 MOTION for Partial Summary Judgment filed by Unimed Pharmaceuticals, Inc., Laboratories Besins Iscovesco. (Ferguson, James) Modified text on 10/18/2005 (dr). (Entered: 10/17/2005)
10/17/05	82	STATEMENT re 81 Response in Opposition to Motion filed by Unimed Pharmaceuticals, Inc., Laboratories Besins Iscovesco. (Ferguson, James) (Entered: 10/17/2005)
10/17/05	83	Response to Statement of Material Facts re 80 MOTION for Partial Summary Judgment filed by Unimed Pharmaceuticals, Inc., Laboratories Besins Iscovesco. (Ferguson, James) (Entered: 10/17/2005)
		* * * * *
10/18/05	90	MOTION for Partial Summary Judgment *of Invalidity of Claims 1-30 of the '894 Patent for Lack of a*

DATE	DOCKET NUMBER	PROCEEDINGS
		Written Description as Required by 35 U.S.C. 112 with Brief In Support by Paddock Laboratories, Inc.. (Attachments: # 1 Brief Memorandum in Support of Paddock's Motion for Partial Summary Judgment of Invalidity of Claims 1-30 of the '894 Patent as Lacking a Written Description as Required by 35 U.S.C. 112, First Paragraph with Respect to the Claimed Ranges of Sodium Hydroxide# 2 Statement of Material Facts Paddock's Statement of Material Facts as to Which There is No Genuine Issue to be Tried in Support of its Motion for Partial Summary Judgment of Invalidity of Claims 1-30 of the '894 Patent Lacking a Written Description Under 35 U.S.C. 112) (Trigg, Mark)—Please refer to http://www.gand.uscourts.gov to obtain the Notice to Respond to Summary Judgment Motion form contained on the Court's website.—(Entered: 10/18/2005)

* * * * *

DATE	DOCKET NUMBER	PROCEEDINGS
11/11/05	97	REPLY to Response to Motion re 80 MOTION for Partial Summary Judgment *in Further Support of its Motion for Partial Summary Judgment as to the Inapplicability and Invalidity of the Certificate of Correction* filed by Paddock Laboratories, Inc.. (Trigg, Mark) (Entered: 11/11/2005)
11/11/05	98	RESPONSE to 82 Statement *of Additional Facts Which are Material and Present a Genuine Issue for Trial* filed by Paddock Laboratories, Inc.. (Trigg, Mark) Modified on 11/14/2005 (dr). (Entered: 11/11/2005)
		* * * * *
12/19/05	106	RESPONSE re 90 MOTION for Partial Summary Judgment *of Invalidity of Claims 1-30 of the '894 Patent for Lack of a Written Description as Required by 35 U.S.C. 112* filed by Unimed Pharmaceuticals, Inc., Laboratories Besins Iscovesco. (Attachments: # 1 Exhibit CC# 2 Exhibit DD# 3 Exhibit

DATE	DOCKET NUMBER	PROCEEDINGS
		EE# 4 Exhibit FF# 5 Exhibit GG# 6 Exhibit HH# 7 Exhibit II # 8 Exhibit JJ# 9 Exhibit KK) (Ferguson, James) (Entered: 12/19/2005)
12/19/05	107	STATEMENT re 106 Response to Motion, filed by Unimed Pharmaceuticals, Inc., Laboratories Besins Iscovesco. (Ferguson, James) (Entered: 12/19/2005)
12/19/05	108	Response to Statement of Material Facts re 90 MOTION for Partial Summary Judgment *of Invalidity of Claims 1-30 of the '894 Patent for Lack of a Written Description as Required by 35 U.S.C. 112* filed by Unimed Pharmaceuticals, Inc., Laboratories Besins Iscovesco. (Ferguson, James) (Entered: 12/19/2005)
		* * * * *
1/19/06	120	REPLY BRIEF re 90 MOTION for Partial Summary Judgment *of Invalidity of Claims 1-30 of the '894 Patent for Lack of a Written Description as Required by 35 U.S.C. 112* filed by Paddock Laboratories,

DATE	DOCKET NUMBER	PROCEEDINGS
		Inc.. (Trigg, Mark) (Entered: 01/19/2006)
1/19/06	121	RESPONSE re 107 Statement *of Additional Facts Which are Material and Present a Genuine Issue for Trial with Respect to Paddock's Motion for Summary Judgment that Claims 1-30 of the '894 Patent are Invalid under 35 ?112* filed by Paddock Laboratories, Inc.. (Trigg, Mark) (Entered: 01/19/2006)
		* * * * *
7/24/06	123	FILED UNDER SEAL—Minute Entry for proceedings held before Judge Thomas W. Thrash Jr.: Status Conference held on 7/24/2006. (Court Reporter David Ritchie.) (ss) Modified access and verified by cdg on 7/27/2006 (dr). (Entered: 07/24/2006)

DATE	DOCKET NUMBER	PROCEEDINGS
7/24/06	124	NOTICE of Telephone Status Conference scheduled for 9/6/06, 2:00 p.m. EST. Plaintiff's counsel to originate call. (ss) (Entered: 07/24/2006)
		* * * * *
9/6/06	127	NOTICE of TELECONFERENCE Hearing: Status Conference set for 9/13/2006 02:00 PM before Judge Thomas W. Thrash Jr.. (ss) (Entered: 09/06/2006)
9/6/06	128	FILED UNDER SEAL—Minute Entry for proceedings held before Judge Thomas W. Thrash Jr.: Telephone Conference held on 9/6/2006. (Court Reporter Pat Tanner.) (dr) Additional attachment(s) added/verified by cdg on 9/7/2006 (dr). (Entered: 09/07/2006)

DATE	DOCKET NUMBER	PROCEEDINGS
9/13/06	129	FILED UNDER SEAL—Minute Entry for proceedings held before Judge Thomas W. Thrash Jr.: Telephone Conference held on 9/13/2006. (Court Reporter Andy Ashley.) (dr) Additional attachment(s) added/verified by cdg on 9/13/2006 (dr). (Entered: 09/13/2006)
9/14/06	130	PROPOSED CONSENT ORDER Consent Judgment and Order of Permanent Injunction. (Grout, Bradley) (Entered: 09/14/2006)
9/15/06	131	CONSENT JUDGMENT AND ORDER OF PERMANENT INJUNCTION (see order for details) Signed by Judge Thomas W. Thrash Jr. on 9/15/06. (dr) (Entered: 09/15/2006)
9/15/06		Civil Case Terminated. (dr) (Entered: 09/15/2006)
7/9/08	132	FILED UNDER SEAL—TRANSCRIPT of Telephone Conference held on 9/13/06, before Judge Thomas W. Thrash, Jr. Court Reporter/Transcriber Andy Ashley,

DATE	DOCKET NUMBER	PROCEEDINGS
		Telephone number 404-215-1478. (dr) (dr). (Entered: 07/09/2008)
7/16/08	133	FILED UNDER SEAL—TRANSCRIPT of Proceedings held on 9/6/06, before Judge Thomas W. Thrash, Jr. Court Reporter/ Transcriber Pat Tanner, Telephone number 404-215-1468. (dr) Modified on 10/7/2008 (dr). Modified on 10/14/2008 to correct docket text (fmm). (Entered: 07/17/2008)

* * * * *

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

Docket No. 01:03-cv-2501-TWT

UNIMED PHARMACEUTICALS, INC., ET AL., PLAINTIFF

v.

WATSON PHARMACEUTICALS, INC., DEFENDANT

No. 01:03-cv-2503-TWT

UNIMED PHARMACEUTICALS, INC., ET. AL., PLAINTIFF

v.

PADDOCK LABORATORIES, INC., DEFENDANT

Filed: Feb. 26, 2004

TRANSCRIPT OF PROCEEDINGS BEFORE THE HONORABLE THOMAS W. THRASH, JR. UNITED STATES DISTRICT JUDGE

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[13]

THE COURT: All Right. Anything else we need to do today?

MR. BLACKSTOCK: Not for the Plaintiff, your Honor.

THE COURT: This has all the appearances of a long, complicated, expensive, difficult case.

Is there anything that I can do to prevent any of [14] that from happening?

I guess not.

All right.

MR. BLACKSTOCK: Your Honor, we will not hesitate to let you know if we believe the court can be of assistance.

MR. WHITE: Your Honor, likewise. I think one thing we can do is as soon as we see a problem coming, if we are able to bring it to your attention before it becomes multiple problems, that would be helpful.

THE COURT: Well, Mr. Blackstock is familiar with how we handle cases, and I am—And I know my Courtroom Deputy cringes every time she hears me say this, but I am available. And if a disagreement can be resolved by telephone conference call rather than having written motions filed and briefs and back and forth and ongoing festering disagreement that drags on for weeks and months at a time, I'd rather resolve it in a telephone call.

Sometimes you need to precede the telephone call with an exchange of letters to me setting forth the nature of the disagreement just so I have some idea of what it is that you're having a problem with, but I'll do anything to avoid having you all file motions. Anything to avoid that.

All right. Thank you very much.

Court's in recess until further order.

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

Case No.: 1:03-CV-2503

UNIMED PHARMACEUTICALS, INC., A DELAWARE CORPORATION, AND LABORATORIES BESINS ISCOVESCO, A DELAWARE CORPORATION, PLAINTIFFS

v.

PADDOCK LABORATORIES, INC. A MINNESOTA CORPORATION, DEFENDANT

Filed: Sept. 15, 2006

CONSENT JUDGMENT AND ORDER OF PERMANENT INJUNCTION

This action for patent infringement (the "Litigation") has been brought by Plaintiff Unimed Pharmaceuticals, Inc. ("Unimed") (a wholly-owned subsidiary of Solvay Pharmaceuticals, Inc. ("Solvay")), and Laboratories Besins Iscovesco ("Besins"), against Defendant Paddock Laboratories, Inc. ("Paddock") for infringement of United States Patent No. 6,503,894 (the "'894 Patent"), covering a pharmaceutical transdermal gel sold under the trademark Androgel® (the "Unimed Product"). Each of Unimed, Solvay, and Besins (the "Plaintiffs") and Paddock, together with its assignee Par Pharmaceutical Companies, Inc. ("Par"), acknowledge there is signifi-

cant risk to each of them associated with the continued prosecution of this Litigation and have consented to judgment through a final settlement, which was encouraged by the Court pursuant to its Local Rules, and as reflected in the consent judgment set forth herein.

Plaintiffs and Paddock, together with Par, have agreed to enter into a good faith final settlement agreement regarding this Litigation on the expectation and belief that this would result in a number of public interest benefits. Pursuant to a settlement agreement and ancillary patent license agreement (the "Agreements") entered into for the final resolution of this Litigation, Par will be able to market the Paddock Product, as defined herein, by no later than 2016, allowing entry of a generic version of the Unimed Product in advance of the 2020 expiration of the '894 Patent, which competition otherwise might not have occurred or been allowed to continue had Plaintiff prevailed on any one of the numerous claims brought against Paddock in the Litigation.

The proposed settlement also would eliminate the substantial litigation costs that would otherwise be incurred by both Plaintiffs and Paddock during the Litigation, while also serving the public interest by saving judicial resources and avoiding the risks to each of the parties associated with infringement. This will afford Plaintiffs and Paddock the opportunity to more productively use money and other resources that would have been spent in the continued prosecution and defense of this Litigation, to the benefit of the Parties and consumers alike, such as by investing more money in marketing,

research and development and education of physicians and patients regarding use and benefits of the Unimed Product, that will facilitate competition and the benefits therefrom approximately five years earlier than could be achieved if the Paddock Product were permanently enjoined during the life of the '894 patent.

In order to effectuate this settlement, Par consents to the jurisdiction of this Court.

Plaintiffs and Paddock now consent to this Judgment and Order of Permanent Injunction (the "Judgment") and

IT IS HEREBY ORDERED, ADJUDGED AND DECREED:

1. This Court has jurisdiction over the parties and subject matter of this action.

2. The '894 Patent is owned by Plaintiffs (or its affiliates) and is valid and enforceable, as asserted in their Complaint against Paddock, in all respects.

3. Paddock and Par acknowledge that the claims of the '894 Patent are valid and enforceable in all respects.

4. Paddock and Par acknowledge that the sale of the product described in its Abbreviated New Drug Application No. 76-744 (the "Paddock Product") would infringe the claims of the '894 Patent, as asserted in the Complaint against Paddock.

5. Paddock assigned its rights in the Paddock Product to Par and Par has assumed certain obligations to defend Paddock in the Litigation.

6. As a result, Paddock and Par are barred from practicing the '894 Patent until

> the earliest of (a) August 31, 2015, provided there is no commercialization sufficient to trigger Hatch-Waxman 180 day exclusivity; (b) the date any Generic Testosterone Gel Product (as defined in the relevant Agreements) is offered for sale in the Territory (as defined in the relevant Agreements); or (c) in any other event, February 28, 2016, by manufacturing, marketing or selling the Paddock Product, pursuant to the terms of the parties' Agreements that permit the practice of the '894 Patent.

7. The submission of Paddock's Abbreviated New Drug Application No. 76-744 under Section 505(j) of the Federal Food, Drug and Cosmetic Act is an act of infringement of the '894 Patent under 35 U.S.C. 271(e)(2)(A).

8. Paddock and Par would infringe the '894 Patent by selling, offering to sell, importing and/or using the Paddock Product.

9. All affirmative defenses, claims and counterclaims, which have been or could have been raised by Paddock in this action with respect to the validity or enforceability of the '894 Patent, are dismissed with prejudice.

10. Except as agreed to by the parties pursuant to the Agreements in settlement of this Litigation or otherwise, Paddock and Par are also hereby enjoined and estopped during the term of the '894 Patent, from making any challenge to the validity or enforceability of the '894 Patent with respect to the claims asserted against Paddock, or from marketing and selling the Paddock Product.

11. The foregoing injunction against Paddock and Par shall take effect immediately upon entry of this Judgment, and shall continue generally with respect to the '894 Patent coterminous with the license grant provided by the Agreements, unless earlier terminated or modified by further order of this Court.

12. The parties waive all right to appeal from this Judgment.

13. This Court shall retain jurisdiction of this action and over the parties for purposes of enforcement of the provisions of this Judgment.

14. Each party is to bear its own costs and attorney's fees.

Dated: Sept. 14, 2006

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SO ORDERED, this 15th day of September, 2006

/s/ THOMAS W. THRASH
THOMAS W. THRASH JR
United States District Judge

Supreme Court, U.S.
FILED
JAN 2 2 2013
OFFICE OF THE CLERK

No. 12-416

In the Supreme Court of the United States

FEDERAL TRADE COMMISSION, PETITIONER

v.

WATSON PHARMACEUTICALS, INC., ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

JOINT APPENDIX
(VOLUME 2)
(UNDER SEAL)

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PETITION FOR A WRIT OF CERTIORARI FILED: OCT. 4, 2012
CERTIORARI GRANTED: DEC. 7, 2012

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The following opinions and orders have been omitted in printing this joint appendix because they appear on the following pages in the appendix to the petition for a writ of certiorari:

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Business Outlook without Settlement

All in MUSD	Solvay	Watson	Par	Other	Total
Solvay wins patent litigation	1,241	0	0	0	1,241
Solvay loses patent litigation	359	152	131	0	642
Mid Point	800	76	66	0	942

Business Outlook with Settlement

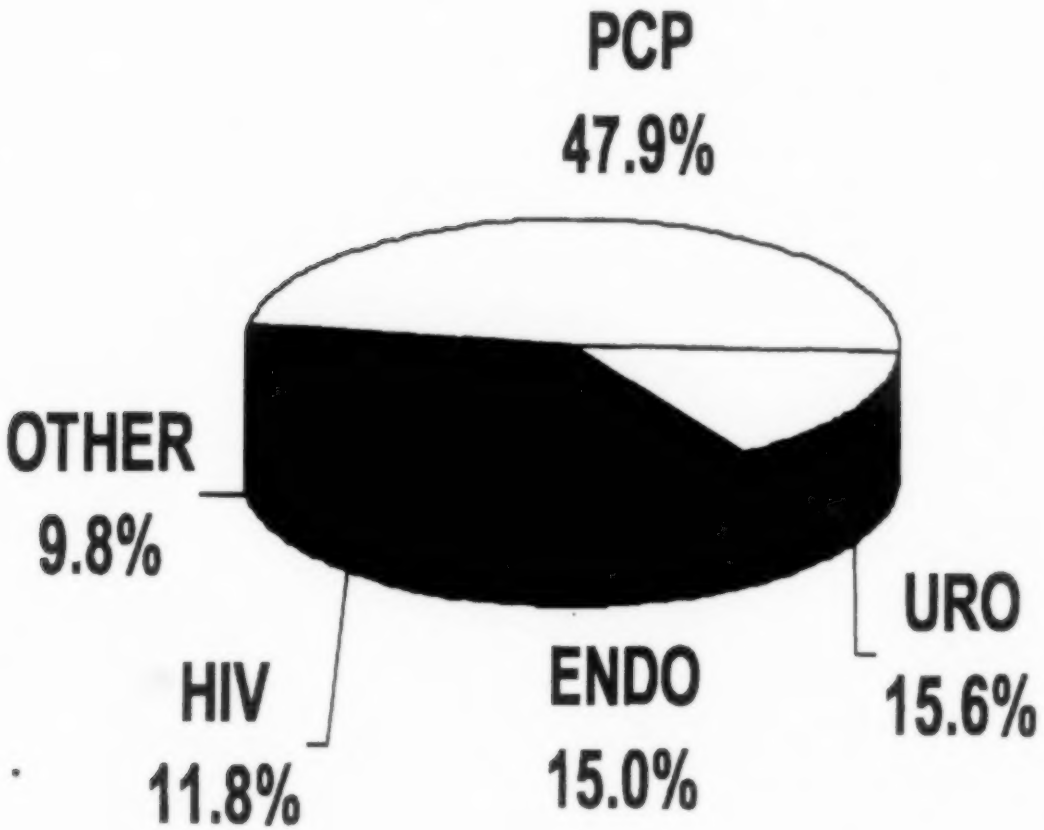
(no additional features such as commercial or manufacturing alliance)

Androgel NPV	Solvay	Watson	Par	Other	Total
2011	786	92	92	92	1,062
2012	900	75	75	75	1,125
2013	959	62	62	62	1,145
2014	1,021	50	50	50	1,171
2015	1,060	41	41	41	1,183

Delta to Mid-point Androgel NPV	Solvay	Watson	Par	Other	Total
2011	(14)	16	27	92	121
2012	100	(1)	10	75	184
2013	159	(14)	(4)	62	204
2014	221	(26)	(16)	50	230
2015	260	(35)	(25)	41	242

Splits of newly created value are NOT attractive to Watson or Par.

Distribution of AndroGel® Prescriptions



Potential Partnership Options: PAR

- **Par Co-promotes Androgel in HIV**
- Potential Compensation Alternatives to Par:
  - Pay 50% to Par for sales above $26 MUSD
  - Pay $30/detail for 10,000 details and 50% of sales above $32 MUSD
  - Carve-out Marinol HIV business and share profits
  - Offer right to manufacture a portion of Androgel
  - Offer right to Marinol Authorized Generic.
  - In-license Par's technology related to Marinol manufacturing/formulation, and pay royalty on existing Marinol business.

Potential Partnership Options: PAR

- Solvay will provide marketing support
- Solvay will train Par sales force
- Solvay will book sales
- Par pays sales force incentive comp
- Par participates in launch of low volume

Potential Partnership Options: WATSON

- Watson Promote Androgel in Urology
- Watson will receive profit sharing for its detailing effort according to following scale:

	Watson Profit Share (%)
2007	50.0%
2008	52.5%
2009	55.0%
2010	57.5%
2011	60.0%
2012	62.5%
2013	65.0%
2014	67.5%
2015	70.0%

Potential Partnership Options: WATSON

- Watson Promote Androgel in Urology
- Solvay will provide marketing support
- Solvay will train Watson sales force
- Solvay will book sales
- Solvay will phase out detailing support in urology universe over 18 months
- Watson pays sales force incentive comp
- Watson participates in launch of low volume
- Option for Watson to launch diabetes indication

Business Logic on Profit Sharing

Urology Based Androgel Business (all in Million USD)

		2007	2014
Androgel Total Brand Sales		$330	$450
% Business in Urology		15%	15%
Androgel Urology Dollar Sales		$50	$68
Androgel Gross Margin	80%	$40	$54
Marketing Expense in Urology	15% of Androgel marketing budget	($3)	($3)
Other commercial support for Urology space	10% of Androgel Urology Sales	($5)	($7)
Net Profit		$32	$44
Watson Share		50%	70%
Watson Net Profit Sharing		**$16**	**$31**

Business Outlook with Settlement

(with urology carve-out for Watson and Pay per detail + baseline structure for Par)

Assume 3-player generic market	Solvay NPV	Watson			Par		
		Generic	Carve-out	Total	Generic	Carve-out	Total
2011	711	82	59	141	82	24	106
2012	779	67	71	138	67	28	95
2013	827	56	82	138	56	31	87
2014	865	46	91	137	46	33	79
2015	888	39	99	138	39	35	74

Delta to Mid-point Androgel NPV	Solvay	Watson	Par	Other	Total
2011				0	0
2012				0	0
2013	16%	37%	13%	34%	100%
2014	35%	33%	7%	25%	100%
2015	45%	31%	4%	20%	100%

Watson/Par Financial View

	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Watson Income if launching generic Androgel($ MUSD)	50	30	20	14	14	14	14	14	14	14
Watson Income with settlement($ MUSD)	15	16	18	20	18	20	19	17	55	45
Delta	(35)	(14)	(2)	6	4	6	5	3	41	31

	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Par Income if launching generic Androgel($ MUSD)	15	30	20	14	14	14	14	14	14	14
Par Income with settlement($ MUSD)	6	7	7	9	6	4	4	3	55	45
Delta	(9)	(23)	(13)	(5)	(8)	(10)	(10)	(11)	41	31

Solvay Financial Impact

Androgel				
	2007	2008	2009	2010
Sales - Five Year Plan	311	312	310	317
Androgel Income- Five Year Plan	149	143	139	138
Impact of Settlement				
Watson Urology Co-Promotion	(19)	(20)	(22)	(23)
Par Co-Promotion/Manufacturing Back-up	(6)	(7)	(7)	(9)
Total Watson/Par	(25)	(27)	(29)	(32)
Redeployment of Reps	10	10	11	11
Besins Contribution	6	6	6	6
Net Impact	(9)	(11)	(12)	(15)
Androgel Income after Settlement	140	132	127	123
Androgel Income-Generic Competition	*24*	*15*	*11*	*10*
Delta	*116*	*117*	*116*	*114*

Watson Counter Offer

	Feature #1	Feature #2	Feature #3	Watson NPV ($ MUSD)
Solvay Offer On 4/24/2006	Exclusivity through Jan, 2015	Start Date: Q1, 2007	Profit Sharing: 50% and grow by 2.5%/year with cap of 70%	99
Watson Counter 4/26/2006	Exclusivity through Jan, 2015	Start Date: Q4, 2006	Profit Sharing: 65% and grow by 1%/year with cap of 70%	122
Delta				23

Annual Payment to Watson ($ MUSD)

2006	2007	2008	2009	2010	2011
0	(15)	(16)	(18)	(20)	(18)
(5)	(19)	(20)	(22)	(23)	(21)

AndroGel Coverage of Prescriber Universe is Very Strong

AndroGel Decile	MDs	All Targets	% Reach	Cum. Reach	URO MDs	URO Targets	% Reach	Cum. Reach
Decile 10	450	443	98%	98%	74	74	100%	100%
Decile 9	972	955	98%	98%	221	217	98%	99%
Decile 8	1,457	1413	97%	98%	339	335	99%	99%
Decile 7	2,014	1942	96%	97%	425	413	97%	98%
Decile 6	2,705	2614	97%	97%	486	463	95%	97%
Decile 5	3,631	3434	95%	96%	572	543	95%	97%
Decile 4	4,991	4593	92%	95%	634	566	89%	95%
Decile 3	7,193	6148	85%	92%	706	548	78%	91%
Decile 1	38,861	16259	42%	63%	1,699	591	35%	71%
Decile 0		23,918			5,682			
Total	74,000	70,268			11,674	4,254		

-DRAFT-
Privileged and Confidential For purposes of settlement negotiations only
Subject to Fed. R. Evid. 408 and all other applicable privileges

PETITIONER'S BRIEF

Supreme Court, U.S.
FILED
JAN 22 2013
OFFICE OF THE CLERK

No. 12-416

In the Supreme Court of the United States

FEDERAL TRADE COMMISSION, PETITIONER

v.

WATSON PHARMACEUTICALS, INC., ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE PETITIONER

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QUESTION PRESENTED

Federal competition law generally prohibits an incumbent firm from agreeing to pay a potential competitor to stay out of the market. See *Palmer* v. *BRG of Ga., Inc.*, 498 U.S. 46, 49-50 (1990) (per curiam). This case concerns agreements between (1) the manufacturer of a brand-name drug on which the manufacturer assertedly holds a patent, and (2) potential generic competitors who, in response to patent-infringement litigation brought against them by the manufacturer, defended on the grounds that their products would not infringe the patent and that the patent was invalid. The patent litigation culminated in a settlement through which the seller of the brand-name drug agreed to pay its would-be generic competitors tens of millions of dollars annually, and those competitors agreed not to sell competing generic drugs for a number of years. Settlements containing that combination of terms are commonly known as "reverse payment" agreements. The question presented is as follows:

Whether reverse-payment agreements are per se lawful unless the underlying patent litigation was a sham or the patent was obtained by fraud, or instead are presumptively anticompetitive and unlawful.

PARTIES TO THE PROCEEDING

The petitioner is the Federal Trade Commission.

Respondents are Watson Pharmaceuticals, Inc., Solvay Pharmaceuticals, Inc., Par Pharmaceutical Companies, Inc., and Paddock Laboratories, Inc.

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In the Supreme Court of the United States

No. 12-416

FEDERAL TRADE COMMISSION, PETITIONER

v.

WATSON PHARMACEUTICALS, INC., ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE PETITIONER

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-36a) is reported at 677 F.3d 1298. The order of the district court (Pet. App. 37a-61a) is reported at 687 F. Supp. 2d 1371.

JURISDICTION

The judgment of the court of appeals was entered on April 25, 2012. A petition for rehearing was denied on July 18, 2012 (Pet. App. 62a-63a). The petition for a writ of certiorari was filed on October 4, 2012, and was granted on December 7, 2012. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

Pertinent provisions of the Sherman Act, 15 U.S.C. 1 *et seq.*, the Federal Trade Commission Act, 15 U.S.C. 41 *et seq.*, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, and Title 35 of the United States

Code are reproduced in an appendix to this brief, App., *infra*, 1a-61a.

STATEMENT

This case presents a question of great economic importance to consumers of pharmaceuticals: how to judge the legality under the federal competition laws of a "reverse payment" agreement between a brand-name drug manufacturer and a potential generic competitor. In such an agreement, a patentee (the brand-name manufacturer) agrees to pay an accused infringer (its would-be generic competitor), and the competitor agrees that it will not enter the market for a specified period of time. The court of appeals affirmed the dismissal of a complaint filed by the Federal Trade Commission (FTC) challenging two related reverse-payment agreements among respondents. Pet. App. 1a-36a. The court held that, "absent sham [patent] litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent," *i.e.*, so long as the patentee does not obtain more protection from competition than would result from a successful infringement suit. *Id.* at 28a.

1. a. Under the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. 301 *et seq.*, the manufacturer of a new drug must obtain approval from the Food and Drug Administration (FDA) of a new drug application (NDA) before marketing the drug. 21 U.S.C. 355(b).[1] The NDA must contain, *inter alia*, a statement of the

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[1] All references in this brief to Title 21 are to the 2000 version of the United States Code. As used in this brief, "drug" refers to a drug, as defined in 21 U.S.C. 321(g)(1), regulated by FDA under 21 U.S.C. 355.

drug's components, proposed labeling that describes the uses for which the new drug may be marketed, and scientific data and other information demonstrating that the drug is safe and effective as labeled. 21 U.S.C. 355(b)(1). A drug approved under the NDA process is often referred to as a "brand-name" drug. See generally *Caraco Pharm. Labs., Ltd.* v. *Novo Nordisk A/S*, 132 S. Ct. 1670, 1675-1676 (2012).

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585, known as the Hatch-Waxman Amendments. Those Amendments are "designed to speed the introduction of low-cost generic drugs to market," *Caraco*, 132 S. Ct. at 1676, while maintaining and refining the patent laws' incentives for innovation. See H.R. Rep. No. 857, 98th Cong., 2d Sess. Pt. 1, at 14-17 (1984) (*House Report*); *id.* Pt. 2, at 5-6; see also *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 669-674 (1990) (explaining how the Hatch-Waxman Amendments address "unintended distortions of [a drug's] patent term produced by the requirement that certain products must receive premarket regulatory approval").

To simplify the approval process for generic drugs, the Hatch-Waxman Amendments provide that, after a brand-name drug's NDA has been approved, and subject to certain periods of NDA exclusivity (see 21 U.S.C. 355(j)(5)(D)), any manufacturer may seek approval to market a generic version by filing an abbreviated new drug application (ANDA) with FDA. See 21 U.S.C. 355(j). The ANDA process does not require the generic manufacturer to provide independent clinical evidence of safety and effectiveness. Instead, the typical ANDA must show, *inter alia*, that the generic drug has the same active ingredient(s) as, and is bioequivalent to, the

brand-name drug to which the proposed generic will be compared. 21 U.S.C. 355(j)(2)(A)(ii) and (iv). See generally *Caraco*, 132 S. Ct. at 1676.

b. "Because," under most circumstances, "FDA cannot authorize a generic drug that would infringe a patent, the timing of an ANDA's approval depends on the scope and duration of the patents covering the brand-name drug." *Caraco*, 132 S. Ct. at 1676. A generic competitor may be able to design its product to satisfy FDA regulations regarding generic drugs, yet avoid infringing a patent that claims only particular features of the brand-name drug product (such as an inactive ingredient, or a coating that affects how the active ingredient is released into the body). See, *e.g.*, *Pharmacia & Upjohn Co.* v. *Mylan Pharms., Inc.*, 170 F.3d 1373, 1377-1379 (Fed. Cir. 1999) (finding no infringement where the generic drug was designed to avoid a patent claiming an inactive ingredient); see generally *Caraco*, 132 S. Ct. at 1676 (noting that drug "patents come in different varieties"); 21 C.F.R. 314.53. In addition, a substantial fraction of fully litigated patent cases have resulted in a finding of patent invalidity. See John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 194, 205 (1998) (*Validity of Litigated Patents*) (finding that 46% of all litigated patents were declared invalid based on examination of all written, final validity decisions by district courts and the Federal Circuit reported in *United States Patent Quarterly* between 1989 and 1996).

The Hatch-Waxman Amendments accordingly establish a litigation framework to facilitate the resolution of patent-related disputes between brand-name and generic manufacturers. Under that framework, a brand-name manufacturer must identify to FDA particular patents

that could reasonably be asserted against someone manufacturing, using, or selling its drug. 21 U.S.C. 355(b)(1); see *Caraco*, 132 S. Ct. at 1676. A generic firm submitting an ANDA must in turn explain how the generic drug can be marketed without infringing those patents. See 21 U.S.C. 355(j)(2)(A)(vii)-(viii). Of particular relevance here, the generic manufacturer may file a "so-called paragraph IV certification," which states that a given patent identified by the brand-name manufacturer "'is invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug.'" *Caraco*, 132 S. Ct. at 1677 (quoting 21 U.S.C. 355(j)(2)(A)(vii)(IV)). "The patent statute treats such a filing as itself an act of infringement, which gives the brand an immediate right to sue." *Ibid.* (citing 35 U.S.C. 271(e)(2)(A)). The Hatch-Waxman Amendments prescribe intricate rules specifying when FDA may and may not approve an ANDA while litigation is pending. See 21 U.S.C. 355(j)(5)(B); p. 6, *infra*. In general, however, the process enables the parties to obtain fairly definitive rulings on patent infringement and invalidity before the would-be generic manufacturer engages in the commercial sale of its product.

c. Congress provided significant incentives for both brand-name and generic manufacturers to engage in paragraph IV litigation. On the generic side, the Hatch-Waxman Amendments reward the first filer of an ANDA containing a paragraph IV certification with a promise of 180 days of exclusivity on the market. See 21 U.S.C. 355(j)(5)(B)(iv) (providing that FDA will not approve an ANDA with a later-filed paragraph IV certification to the same patent as an earlier-filed ANDA for at least 180 days after either a court decision finding the patent invalid or not infringed, or the first commercial market-

ing of the drug under the first ANDA, whichever is earlier). That period of exclusivity ensures that the first filer does not face price competition from other generic entrants during the period of exclusivity, and it gives that manufacturer a head start in reaching commercial arrangements with large purchasers. According to the generic pharmaceutical industry's leading trade association, the "vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period." Comments of Generic Pharm. Ass'n to FTC on Authorized Generic Drug Study 2 (June 27, 2006), http://www.ftc.gov/os/comments/genericdrug study3/062806gpha.pdf.

The Hatch-Waxman Amendments also encourage (though they do not require) the brand-name manufacturer to respond to a paragraph IV certification by promptly suing the generic applicant for patent infringement. Such a suit triggers an automatic stay of FDA approval of the ANDA for 30 months. 21 U.S.C. 355(j)(5)(B)(iii). That stay is extremely valuable to the brand-name manufacturer because it provides the rough practical equivalent of an automatic preliminary injunction against generic competition during the first 30 months of any infringement litigation.

d. In cases litigated to decision, would-be generic competitors have prevailed nearly three quarters of the time in paragraph IV litigation against brand-name manufacturers. See FTC, *Generic Drug Entry Prior to Patent Expiration* 10, 19-20 (July 2002), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf (finding that generic competitors prevailed over brand-name manufacturers with respect to 73% of the drug products that were the subject of a court decision in paragraph IV litigation initiated between 1992 and 2000); see also Paul

M. Janicke & LiLan Ren, *Who Wins Patent Infringement Cases?*, 34 AIPLA Q.J. 1, 20 chart 1 (2006) (finding that, between 2002 and 2004, accused infringers had a 70% success rate in Federal Circuit decisions with a final ruling on drug-patent claims).

Paragraph IV litigation continues to be an important route for the entry of generic competition. The patent portfolios of brand-name drug manufacturers have grown in recent years with the addition of "secondary" patents, such as "patents on chemical variants, alternative formulations, methods of use, and relatively minor aspects of the drug." C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. Empirical Legal Stud. 613, 615, 619-623 (2011); see Amy Kapczynski et al., *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, PLOS ONE, e49470, at 6 (Dec. 2012) (analyzing 432 new drugs with patent protection approved by FDA between 1988 and 2005, and concluding that "patents with secondary claims are extremely common" and that such patents "on average add substantial time to the nominal patent terms enjoyed by drugs"); cf. *Caraco*, 132 S. Ct. at 1676 (noting that patents held by brand-name manufacturers "come in different varieties" and are not limited to patents that "protect[] the drug compound itself"). Those secondary patents may be particularly susceptible to being avoided, in whole or in part, by generic competitors.

e. The 2011 domestic market for drugs totaled approximately $245 billion. See IMS Inst. for Healthcare Informatics, *The Use of Medicines in the United States: Review of 2011*, at 27 (Apr. 2012), http://www.imshealth.com/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/

IHII_Medicines_in_U.S_Report_2011.pdf. Brand-n drugs accounted for 18% of total prescriptions for c and biologics (which include products such as vacci *id.* at 16, but 73% of total spending, *id.* at 27. Tha parity reflects, *inter alia*, the monopoly reward patent laws offer for brand-name innovatio[illegible].

As generic competition sets in, prices for ge drugs fall, on average to about 15% of what the bra manufacturer was charging. See FTC, *Pay-for-D How Drug Company Pay-Offs Cost Consumers lions* 8 (2010), http://www.ftc.gov/os/2010/01/10011 fordelayrpt.pdf (*Pay-for-Delay Report*). At the time, the brand-name manufacturer loses about 90 cent of its market share (by unit sales) to its ge competitors. *Ibid.* Those substantially lower p benefit a wide range of participants in the marke cluding individuals (who may pay for drugs ou pocket), health-insurance companies (which reimb the cost of prescription drugs), employers (whicl health-insurance premiums), and taxpayers (who port programs such as Medicare and Medicaid). savings generated by market competition from ge pharmaceuticals amount to many tens of billions o lars annually. See U.S. Gov't Accountability Off., *R No. GAO-12-371R, Savings from Generic Drug Us* (2012), http://www.gao.gov/assets/590/588064.pdf cussing studies).

Given the significant difference between mon and competitive drug prices, a brand-name manufa er has a strong economic incentive to induce its w be generic competitor to forgo competition. And the generic manufacturer will profit if it preva paragraph IV litigation and enters the market, its its will be much less than the brand-name manufac

stands to lose. As a result, both the brand-name and generic manufacturers may benefit (at the expense of consumers) if the brand-name manufacturer agrees to share its monopoly profits in exchange for the generic manufacturer's agreement to defer its own entry into the market. See, *e.g.*, C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 635-636 (2009) (*Aggregate Approach to Antitrust*).

2. The agreements at issue in this case concern AndroGel®, a prescription gel used to treat hypogonadism, a medical condition involving the underproduction of testosterone associated with advancing age, certain cancers, diabetes, and HIV/AIDS, among other conditions. Second Amended Complaint (Complaint) ¶ 33, J.A. 37. Besins Healthcare, S.A., developed AndroGel® and licensed the marketing rights in the United States to respondent Solvay Pharmaceuticals, Inc. in 1995. *Id.* ¶ 32, J.A. 36-37. FDA approved AndroGel® in February 2000, and in 2007 the product had sales of more than $400 million. *Id.* ¶¶ 33, 34, J.A. 37.

Although patents on the synthesized testosterone used in AndroGel® expired decades ago, in August 2000 Solvay applied for a patent on certain pharmaceutical formulations containing specified amounts of testosterone and certain other ingredients. Complaint ¶¶ 31, 38-39, J.A. 36-38. In January 2003, the Patent and Trademark Office (PTO) issued a patent to Solvay. *Id.* ¶ 42, J.A. 39. In May 2003, respondents Watson Pharmaceuticals, Inc., and Paddock Laboratories, Inc., submitted separate ANDAs to FDA seeking approval for generic versions of AndroGel®. *Id.* ¶ 44, J.A. 39-40. The Watson and Paddock ANDAs each included a paragraph IV certification asserting that the applicant's

generic product would not infringe Solvay's formu patent and that the patent was invalid. *Ibid.* Sl after Paddock submitted its ANDA, responden Pharmaceutical Companies, Inc., agreed to partne Paddock by sharing in Paddock's litigation cost eventually, promoting Paddock's generic versi AndroGel®. *Id.* ¶ 46, J.A. 40.

In August 2003, Solvay sued Watson and Paddo patent infringement, Complaint ¶ 47, J.A. 40, trigg the 30-month stay of ANDA approval provided U.S.C. 355(j)(5)(B)(iii). During the ensuing pate gation, Watson and Paddock amassed substanti dence that their products would not infringe So formulation patent and that the patent was in Complaint ¶¶ 86-89, J.A. 53-55. By late 2005, W and Paddock had filed motions for summary judg detailing much of this evidence. *Id.* ¶ 90, J.A. 55.

In January 2006—at the expiration of the 30-r stay of FDA approval, and while the patent litig was still pending—FDA approved Watson's A Complaint ¶ 52, J.A. 41. Watson and Paddock/P pected to begin selling their products no later than *Id.* ¶ 54, J.A. 42. They predicted that prices for ge versions of AndroGel® would fall to as little as 1 of the price of Solvay's branded AndroGel®. *Id.* 51, J.A. 41. Solvay anticipated losing approxi 90% of its AndroGel® sales within a year afte launch of a generic version, cutting its profits by million a year. *Id.* ¶ 49, J.A. 41. Solvay's U.S. advised his European superiors that Watson launch generic AndroGel® sometime in 2006. *Id.* J.A. 42.

Solvay therefore internally evaluated the pros for a settlement that would avoid that outcome.

plaint ¶ 57, J.A. 43.[2] Solvay concluded that Watson and Paddock/Par might prefer agreeing to defer entry into the market rather than face an uncertain outcome in litigation, *ibid.*, but that they would not accede to a generic entry date in 2015 (which was significant to Solvay because it anticipated shifting its customers by that date to a new product with no generic equivalent, *id.* ¶ 63, J.A. 45-46). Payments, however, changed the equation. Solvay calculated that if it were to share AndroGel® monopoly profits with Watson and Paddock/Par, a settlement with a generic entry date in 2015 would be more profitable for each respondent than continued litigation. *Id.* ¶ 58, J.A. 43-44.

As Solvay had anticipated, Watson and Paddock/Par each insisted on receiving a payment in exchange for assenting to Solvay's preferred 2015 generic entry date. Complaint ¶¶ 61, 67, 70-71, 79, J.A. 44-45, 46-47, 50. Solvay ultimately agreed to pay Watson an estimated $19-30 million annually, ostensibly for Watson to market AndroGel® to urologists. *Id.* ¶¶ 65-67, J.A. 46. Solvay agreed to pay $2 million annually to Paddock and $10 million annually to Par, ostensibly for Paddock to serve as a back-up supplier of AndroGel® and for Par to market the drug to primary care physicians. *Id.* ¶¶ 74-75,

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[2] Solvay's internal analysis is attached to the Complaint as Exhibit A and reprinted, under seal, at J.A. 103-116. On December 19, 2012, the district court agreed with the FTC that the exhibit should be made public, in view of the passage of time, evolution of the AndroGel® market, and the heightened public interest attending this Court's grant of certiorari. Dkt. 202. Solvay then sought and obtained a stay from the Eleventh Circuit pending its appeal of the unsealing order. No. 12-16488 Docket entry (Jan. 10, 2013). We therefore limit our discussion to the matters alleged in the public complaint.

J.A. 48-49.[3] Those agreements made economic s only as a mechanism for Solvay to pay its nascent g ic competitors to delay competing with it, becaus marketing agreements and the back-up manufact deal had little value to Solvay. *Id.* ¶¶ 81-85, J.A. 5 The reverse-payment agreements eliminated pot competition that could have saved consumers hun of millions of dollars a year. *Id.* ¶¶ 96, 98, J.A. 57-

3. The FTC filed suit under Section 5 of the Fe Trade Commission Act (FTC Act), 15 U.S.C. 45, to lenge respondents' agreements. The FTC asserte the generic competitors' agreements not to con with Solvay, in exchange for payments from S were unfair methods of competition. Complaint ¶ 108, J.A. 60-61. The FTC further alleged that S had unlawfully extended its monopoly on Andro not on the basis of its formulation patent, but by pensating its potential competitors. *Id.* ¶¶ 110-111 61-62. The FTC sought declarations that the a ments and Solvay's course of conduct were unlawfu a permanent injunction against the parties' co pursuant to 15 U.S.C. 53(b). J.A. 62-63 (Com Prayer for Relief).

4. The district court dismissed the FTC's com for failure to state a claim. Pet. App. 37a-61a. Re

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[3] While this case was pending in the court of appeals, Par re that it had terminated its co-promotion agreement with Solvay that agreement's scheduled expiration in exchange for a $2 payment. See Par Pharm. Cos., Inc., Annual Report (Form 1(38 (Feb. 24, 2011). The FTC has not had investigation or dis into matters surrounding that development, such as the con Par's continuing agreements with Solvay respecting AndroGe any event, subsequent developments would not bear on the allegation that Par and Solvay's agreement not to compete is ful.

on *Valley Drug Co.* v. *Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003), cert. denied, 543 U.S. 939 (2004), and *Schering-Plough Corp.* v. *FTC*, 402 F.3d 1056 (11th Cir. 2005), cert. denied, 548 U.S. 919 (2006), the court held the complaint insufficient because it "d[id] not allege that the settlements between the Defendants exceed the scope of [Solvay's] patent." Pet. App. 48a. The district court emphasized that the settlements exclude generic versions of AndroGel® from the market only until August 31, 2015, which is "five years less exclusion than [Solvay's] patent" provides. *Ibid.* The court concluded that, absent allegations that the patent litigation itself was a sham, neither "the likelihood that [Solvay] could assert its claims in court and win" nor Solvay's promise to pay tens of millions of dollars annually to its potential competitors was a relevant consideration. *Id.* at 49a-52a.[4] The court also rejected, as inconsistent with circuit precedent, the FTC's contention that reverse-payment agreements should be treated as presumptively unlawful. *Id.* at 51a-52a.

5. The court of appeals affirmed. Pet. App. 1a-36a. In its brief to the court of appeals, the FTC recognized that the Eleventh Circuit had already suggested on three occasions—in *Valley Drug*, *Schering-Plough*, and *Andrx Pharmaceuticals, Inc.* v. *Elan Corp.*, 421 F.3d 1227, 1234-1236 (2005)—that reverse-payment agree-

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[4] The district court has since held as a matter of law, in private antitrust litigation challenging the reverse-payment agreements at issue here, that Solvay's infringement suits were not objectively baseless. *In re Androgel Antitrust Litig. (No. II)*, No. 09-MD-2084, 2012 WL 5352986 (N.D. Ga. Oct. 30, 2012). The plaintiffs have appealed that ruling, and the Eleventh Circuit has stayed proceedings in those appeals pending this Court's decision in this case. *E.g.*, *Rochester Drug Co-Op, Inc.* v. *Unimed Pharms. Inc.*, No. 12-15562, Docket entry (11th Cir. Nov. 26, 2012).

ments were subject to very limited antitrust scr
The court of appeals rejected the FTC's efforts t
or distinguish those decisions, see Gov't C.A. Br.
explaining that, under its prior rulings, the brand
manufacturer's patent made "traditional [anti
analysis * * * inappropriate." Pet. App. 23a. In
the court held that, "absent sham litigation or fr
obtaining the patent, a reverse payment settlem
immune from antitrust attack so long as its anticor
tive effects fall within the scope of the exclusi
potential of the patent." *Id.* at 28a. The court of a
stressed that, under its approach, "a patent's
exclusionary power * * * does not count." *Id.* a
Rather, the court explained, what matters is the pa
"*potential* exclusionary power," *ibid.*, which the
described as "the exclusionary rights appearing
patent's face and not the underlying merits of t
fringement claim." *Id.* at 26a n.8.

The FTC also urged that prior Eleventh Circui
sions had misapplied general antitrust principle
had failed to heed congressional policy regarding
disputes affecting generic drugs. It contended
treating the issue *res nova*, reverse-payment
ments should be recognized as presumptively unl
under the antitrust laws because "[i]n the abse
another explanation for them, * * * the patent h
is obtaining a greater degree of exclusion than it
have achieved without the payment * * * or wi
expected outcome of litigation." Gov't C.A. Br. 5
id. at 43-56. The court of appeals acknowledge
FTC's fundamental position, Pet. App. 4a, but ad
to its precedent.

6. In a decision rendered shortly after the Ele
Circuit's decision in this case, the Third Circuit rej

the so-called scope-of-the-patent approach applied by the Eleventh Circuit below, explaining that in practice, that test "does not subject reverse payment agreements to any antitrust scrutiny." See *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 214 (2012), petitions for cert. pending, No. 12-245 (filed Aug. 24, 2012) and No. 12-265 (filed Aug. 29, 2012). The Third Circuit found "no significant support" for the scope-of-the-patent approach's "almost unrebuttable presumption of patent validity." *Ibid.* The court further explained that "the effectively conclusive presumption that a patent holder is entitled to exclude competitors is particularly misguided" in cases where infringement is at issue and there is no presumption favoring the patent holder's claim. *Ibid.* The Third Circuit held instead that reverse-payment agreements are subject to a "quick look rule of reason analysis" under which "any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market [is] *prima facie* evidence of an unreasonable restraint of trade." *Id.* at 218.

7. The Eleventh Circuit denied the FTC's petition for rehearing en banc, which urged the court to revisit its precedent and treat reverse-payment agreements as presumptively unlawful. Pet. App. 62a-63a.

SUMMARY OF ARGUMENT

I. Reverse-payment agreements should be treated as presumptively unlawful because they closely resemble the sorts of horizontal agreements to suppress competition that have previously been condemned under the antitrust laws. Such agreements have been treated as per se unlawful even if the would-be competitor's prospects of market entry were uncertain at the time the agreement was formed. When parties to paragraph IV litigation settle a case by simply agreeing on a compro-

mise date of generic entry, the generic manufacturer's incentive is to negotiate the earliest possible entry date in order to maximize its own profits. That incentive ensures that consumer interests will receive significant protection in the negotiating process, and it provides reason for confidence that the agreed-upon entry date reflects the parties' own assessment of the likely litigation outcome. By contrast, a Hatch-Waxman settlement that includes a reverse payment allows the brand-name manufacturer to co-opt its rival by sharing the monopoly profits that result from an artificially prolonged period of market exclusivity.

Nothing in the Patent Act legitimizes the use of reverse payments as a settlement term. Although a patentee's good-faith effort to enforce its patent through litigation cannot subject it to antitrust liability, a patentee who chooses that course accepts the risk that it might lose. And while a Hatch-Waxman settlement without a reverse payment should ordinarily raise no antitrust concern, there are sound reasons to treat reverse-payment settlements differently. Such agreements depart from usual settlement practices by giving the generic manufacturer a monetary payment that it could not have hoped to obtain from the brand-name manufacturer even by winning the lawsuit. The reverse payment also severs the alignment of interests that would otherwise exist between the generic manufacturer and consumers when the parties to paragraph IV litigation negotiate a compromise date of generic entry.

Reverse-payment agreements also subvert the balance of competing policies struck in the Hatch-Waxman Amendments. Congress established the paragraph IV patent litigation framework to facilitate early and definitive resolution of patent disputes, and nothing in the

Amendments contemplates that a patentee will pay an accused infringer to escape that framework. Moreover, the Amendments reflect a balance of benefits for generic manufacturers and protections from competition for brand-name manufacturers, a balance that would be upset by giving a brand-name manufacturer the added opportunity to purchase still more protection by sharing its monopoly profits.

Reverse-payment agreements should accordingly be treated as presumptively anticompetitive under a "quick look" rule of reason analysis. The defendants in the antitrust suit should in turn be given an opportunity to rebut the presumption. The principal means of rebuttal would be through proof that the payment was instead consideration for unrelated property or services, or that the payment was commensurate with the litigation costs that the brand-name manufacturer would otherwise have borne. In rare circumstances, other unusual business or litigation justifications may also supply a rebuttal. Absent such a rebuttal, however, a reverse-payment agreement should be held unlawful. Such a "quick look" approach of treating reverse-payment agreements as presumptively anticompetitive would preserve the salutary incentives Congress has provided for brand-name and generic manufacturers to resolve paragraph IV litigation in alternative ways that do not undo the manufacturers' competitive relationship.

II. The "quick look" approach, which treats reverse-payment agreements as presumptively unlawful, is superior to the other modes of analysis that have emerged in the case law. In particular, the scope-of-the-patent approach applied by the court below gives no meaningful antitrust scrutiny to reverse-payment agreements, notwithstanding their manifest anticompetitive potential.

That approach effectively assumes that the rele
patent is valid and infringed, even though generic m
facturers often prevail in paragraph IV litigation,
even though one party to every reverse-payn
agreement is a generic manufacturer who has previo
certified that the patent is invalid or will not be
fringed. Given the profitability of reverse-payn
agreements, if this Court were to adopt the scope
the-patent approach as the applicable nationwide r
brand-name manufacturers would have little reason
to offer their potential generic competitors paym
not to compete, and the generic manufacturers w
have little reason to refuse. The increased freque
and severity of reverse-payment agreements woul
turn, substantially increase prescription drug costs
consumers.

The public policy in favor of voluntary settlen
does not justify the scope-of-the-patent rule. The "q
look" approach leaves manufacturers substantial
tude to settle their disputes so long as they do not ut
reverse payments. The financial incentives create
the Hatch-Waxman Amendments likewise provid
justification for the scope-of-the-patent appro
Those incentives are not different in kind from th
centives of patentees in other infringement suits,
reverse payments appear to be essentially unkn
outside the Hatch-Waxman context. In any event, t
extent that some brand-name manufacturers face e
cially strong pressure to settle particular Ha
Waxman suits, generic manufacturers can exploit
pressure either by negotiating an especially early e
date or by accepting a reverse payment in exchang
delaying competition. Although the scope-of-the-pa
approach treats those as equally legitimate negotia

tactics, requiring the generic manufacturer to pursue the former accords with the consumer-protective purposes of the antitrust laws.

III. The FTC's complaint states a claim for relief under the "quick look" approach. It alleges that, in settling paragraph IV litigation, respondents entered into agreements under which the brand-name manufacturer promised substantial monetary payments and the generic manufacturers agreed to refrain from marketing competing products for the next nine years.

ARGUMENT

I. TREATING REVERSE-PAYMENT AGREEMENTS AS PRESUMPTIVELY UNLAWFUL SERVES THE PURPOSES OF COMPETITION LAW, PATENT LAW, AND THE HATCH-WAXMAN AMENDMENTS

Reverse-payment agreements exist at the intersection of competition law, patent law, and the Hatch-Waxman Amendments' framework for regulating generic drugs. Because reverse-payment agreements closely resemble other horizontal agreements between competitors that this Court has categorically condemned, respondents' defense of the practice necessarily depends on the contention that either the Patent Act or the Hatch-Waxman Amendments implicitly legitimize conduct that would ordinarily be viewed as a paradigmatic antitrust violation. That argument is misconceived. Absent unusual circumstances, reverse-payment agreements disserve rather than further the purposes of patent law and the Hatch-Waxman Amendments, and they should accordingly be treated as presumptively unlawful.

A. Reverse-Payment Agreements Closely Resemble Horizontal Agreements Between Competitors That Per Se Unlawful Under Federal Competition Law

1. An incumbent firm's agreement to pay a pote competitor to stay out of the market is ordinarily demned as a per se violation of Section 1 of the She Act, 15 U.S.C. 1. See *Palmer* v. *BRG of Ga., Inc.* U.S. 46, 49-50 (1990) (per curiam). "Under the She Act a combination formed for the purpose and wit effect of raising, depressing, fixing, pegging, or sta ing the price of a commodity in interstate or fo commerce is illegal *per se*." *United States* v. *Soc Vacuum Oil Co.*, 310 U.S. 150, 223 (1940). In ger "raising price, reducing output, and dividing ma have the same anticompetitive effects." *Calif Dental Ass'n* v. *FTC*, 526 U.S. 756, 777 (1999) (cit omitted). Such agreements therefore are ordi condemned as unlawful per se. See *Catalano, I Target Sales, Inc.*, 446 U.S. 643, 647 (1980) (per cu (reviewing a wide range of horizontal agreement tween competitors that this Court has condemn unlawful per se). From an economic perspective, agreements between rivals are anticompetitive be they directly restrict output and raise price. See Dennis W. Carlton & Jeffrey M. Perloff, *Modern I trial Organization* 123-125 (4th ed. 2005).

Those bedrock principles of competition law even if the would-be competitor's prospects of succ market entry were uncertain when the agreemen formed. See *United States* v. *Griffith*, 334 U.S 10 (1948) ("The anti-trust laws are as much violated b prevention of competition as by its destructi 12 Herbert Hovenkamp, *Antitrust Law* ¶ 2030b, a (3d ed. 2012) (*Antitrust Law*) ("[T]he law does no

done the purchase of protection from uncertain competition any more than it condones the elimination of actual competition."); *Engine Specialties, Inc.* v. *Bombardier Ltd.*, 605 F.2d 1, 9 (1st Cir. 1979) ("Agreements not to compete among potential competitors as well as among actual competitors are forbidden."), cert. denied, 446 U.S. 983, and 449 U.S. 890 (1980); cf. *United States* v. *Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir.) (en banc) (per curiam) (exclusionary conduct is unlawful when it "is aimed at producers of nascent competitive technologies as well as when it is aimed at producers of established substitutes"), cert. denied, 534 U.S. 952 (2001).

2. Competitors often have a strong economic self-interest in entering into such horizontal agreements. In the pharmaceutical industry, for example, standard economic theory predicts that a brand-name manufacturer's monopoly profits will greatly exceed the combined profits that the brand-name and generic manufacturers could earn if they competed against each other for sales of the same drug. The brand-name manufacturer's monopoly profits are large enough to pay its would-be generic competitors more than they could hope to earn if they entered the market, while still leaving the brand-name manufacturer greater profits than it could earn in the face of generic competition. See C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1581-1582 (2006) (*Pharmaceutical Patent Settlement*). If no legal impediment to such agreements existed, both the brand-name and generic manufacturers could benefit financially if the generic company agreed to defer competition in exchange for a share of the resulting monopoly profits. See 12 *Antitrust Law* ¶ 2046c1, at 338 ("In such cases [an] agreement effec-

tively 'preserves' the patent, thus giving the [brand-name and generic manufacturers] the joint-maximizing, or monopoly, output.").

These incentives are particularly apparent when the brand-name manufacturer and its potential generic competitor are settling paragraph IV litigation. When they select a date on which generic entry will be permitted under their settlement, the two manufacturers are not simply deciding how a fixed pool of profits will be divided between them (as might be the case in the settlement of an ordinary commercial dispute), but are also controlling how large the combined pool will be. Even though the generic manufacturer earns no profits during a year of brand-name exclusivity, the total profits of the two firms taken together (*i.e.*, the brand-name manufacturer's monopoly profits plus zero profits for the generic manufacturer) will be greater than the brand-name and generic manufacturers' combined profits during a year when the firms compete. Those extra profits will come at the expense of consumers, who pay more for drugs during a period of brand-name exclusivity and consequent monopoly pricing. By agreeing to a later date of generic entry, the brand-name and generic manufacturers can extend the period of monopoly pricing and thereby increase total profits, while harming consumers. See, *e.g.*, *Aggregate Approach to Antitrust*, 109 Colum. L. Rev. at 635-636.

Of course, the potential maximization of "total" profits for a year of brand-name monopoly will have no practical benefit for a generic manufacturer whose share of that total is zero. Thus, when brand-name and generic drug manufacturers simply negotiate a compromise date of generic entry, the generic manufacturer's incentive is to negotiate the earliest entry date it can, consistent

with the parties' respective assessments of the likely outcome of the suit. Like the competing supplier of bar-exam review courses in *Palmer*, see 498 U.S. at 47, the generic manufacturer will have no reason to gratuitously agree to withdraw from competition simply to enable the brand-name manufacturer to obtain greater revenues than the two companies together could earn in a competitive environment. In that circumstance, the financial interest of the generic manufacturer in maximizing its own profits is aligned with the interest of consumers in hastening the advent of generic competition and consequent lower prices.

The generic manufacturer's incentives are different, however, if it is offered a share of the profits the brand-name manufacturer could earn during an extended period of monopoly conditions. That was the function of the revenue-sharing arrangement in *Palmer*, 498 U.S. at 47, 49-50, and it is the usual function of a reverse payment in the pharmaceutical context. In substance, a reverse-payment agreement is a mechanism for inducing the generic manufacturer to forgo its own output, as a way to increase the manufacturers' combined profits, at the expense of competition and consumer welfare. Such "treaties with * * * competitors," *United States* v. *Citizens & S. Nat'l Bank*, 422 U.S. 86, 116 (1975), are "the supreme evil of antitrust: collusion," *Verizon Commc'ns, Inc.* v. *Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 408 (2004) (*Trinko*).

3. Solvay's analysis of the settlement of paragraph IV litigation with Watson and Paddock/Par vividly illustrates the economic analysis outlined above. In general, Solvay's analysis revealed that, absent a reverse payment, the parties had the opposing interests that one expects competitors to have: An earlier agreed-upon

generic entry date would have been acceptable to generic manufacturers, because that would yield pr that equaled or exceeded the profits the generic m facturers would expect from continuing to litigate. Complaint ¶¶ 57, J.A. 43. By contrast, a later agr upon entry date made settlement more profitable Solvay, because that would preserve its monopoly p its. *Id.* ¶ 58, J.A. 43-44. But Solvay recognized that could pay its potential competitors, then all pa would earn more profit by delaying competition. *I* Solvay therefore pursued a strategy of paying its po tial generic competitors to agree to a later entry d which in turn increased the combined pool of pr available to all the manufacturers, at the expens consumers.

B. Reverse-Payment Agreements Do Not Further, An Important Respects Disserve, The Purposes Of The tent Act

The FTC brought suit in this case under Section the FTC Act, 15 U.S.C. 45, which prohibits "[u]n methods of competition in or affecting commerce." U.S.C. 45(a)(1). Just as an agreement not to com among potential competitors ordinarily is a prohib "contract * * * in restraint of trade" under Secti of the Sherman Act, 15 U.S.C. 1, such an agreeme ordinarily an "[u]nfair method[] of competition" scribed by the FTC Act. See, *e.g.*, *California De* 526 U.S. at 762 n.3 ("The FTC Act's prohibition of u competition and deceptive acts or practices overlaps scope of § 1 of the Sherman Act aimed at prohibi restraint of trade.") (citation omitted). The ques presented in this case is whether, and under what cumstances, an agreement not to compete ceases t

"unfair" because it is encompassed within the settlement of ongoing patent litigation.

Under the Patent Act and this Court's precedents, a brand-name manufacturer's good-faith effort to enforce its patent through litigation cannot subject it to liability under the antitrust laws, even though the purpose of such litigation is to forestall competition. Nor should antitrust liability ordinarily attach to a settlement by which the parties to paragraph IV litigation simply agree on a compromise date of generic entry. Although such an agreement entails a restriction of competition, that is the natural subject of compromise in a suit whose very aim is to restrict competition. Significantly, the extent of that restriction is kept in check by the generic manufacturer's financial incentive to negotiate the earliest possible entry date that the strength of its bargaining position enables it to obtain, in turn affording some assurance that the agreed-upon entry date reflects the strength of the patentee's infringement claim. That justification evaporates, however, when the parties' agreement provides for a substantial reverse payment, because such a payment can be expected to redirect the generic manufacturer's financial incentive into preserving the brand-name manufacturer's monopoly for as long as that monopoly will be profitable.

1. A valid patent confers a right to exclude others from practicing the invention it claims. 35 U.S.C. 154(a)(1). But simply holding a patent does not result in the automatic exclusion of potential rivals who choose to test the patent's validity or scope in court. See *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 214-215 (3d Cir. 2012), petitions for cert. pending, No. 12-245 (filed Aug. 24, 2012) and No. 12-265 (filed Aug. 29, 2012). To enforce a contested patent, a patentee must prove that the

accused product or process falls within the scope of the patent's claims as properly construed. See *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370, 374 (1996). And while a patentee enjoys a statutory presumption that its patent is valid, see 35 U.S.C. 282, that presumption is rebuttable, see *Microsoft Corp.* v. *i4i Ltd. P'ship*, 131 S. Ct. 2238, 2245 (2011); *Lear, Inc.* v. *Adkins*, 395 U.S. 653, 670 (1969), and patents are held invalid despite it, see *Validity of Litigated Patents*, 26 AIPLA Q.J. at 205.

A patentee may enforce its patent through (non-sham) litigation without fear of antitrust consequences. See *Walker Process Equip., Inc.* v. *Food Mach. & Chem. Corp.*, 382 U.S. 172, 176-177 (1965); see also *Professional Real Estate Investors, Inc.* v. *Columbia Pictures Indus., Inc.*, 508 U.S. 49, 56-57 (1993). When a patentee chooses this protected avenue of enforcement, however, it faces the risk that it could lose. The consequences of that possibility are magnified by the rule of *Blonder-Tongue Laboratories, Inc.* v. *University of Illinois Foundation*, 402 U.S. 313, 350 (1971), that a determination of patent invalidity may be given collateral estoppel effect against the patentee in a subsequent infringement suit against a different party. The risks attendant to patent enforcement are part of the balance struck by the patent laws.

2. Although the Patent Act does not expressly authorize the use of voluntary settlements to resolve patent-infringement suits, it is well-established that such agreements do not generally violate the antitrust laws. See *Standard Oil Co. (Ind.)* v. *United States*, 283 U.S. 163, 171 (1931) (stating, in the patent context, that "[w]here there are legitimately conflicting claims or threatened interferences, a settlement by agreement,

rather than litigation, is not precluded by the [Sherman] Act"). At the same time, private agreements that settle patent litigation do not enjoy the antitrust immunity afforded to litigation itself. Cf. *United States* v. *Masonite Corp.*, 316 U.S. 265, 277 (1942) ("Beyond the limited monopoly which is granted, the arrangements by which the patent is utilized are subject to the general law.").

Thus, while the parties to patent-infringement litigation have substantial latitude to settle their differences in accordance with the settlement practices commonly used in private lawsuits, the antitrust analysis requires a nuanced examination of the specific terms of the parties' agreement. When the parties to a Hatch-Waxman settlement simply agree upon a compromise date of generic entry, with no money or similar consideration flowing from the brand-name to the generic manufacturer, the settlement is unlikely to raise antitrust concerns. That is so for two basic reasons.

First, an agreement of that nature fits comfortably within traditional understandings of the way in which private litigation is generally settled. The typical settlement provides for a compromise outcome that falls between the dispositions that would result from judgments in favor of the plaintiff and defendant respectively. In paragraph IV litigation, a judgment in favor of the brand-name manufacturer would allow continued exclusion of generic competition until the patent expires, while a judgment for the generic manufacturer would facilitate immediate generic entry. An agreed-upon date of generic entry in between those endpoints is closely analogous to the typical settlement of a suit for money damages, under which the defendant agrees to pay some portion of what it would be required to pay if it litigated and lost. And although such a compromise settlement of

paragraph IV litigation will entail the parties' agreement not to compete, that feature alone is not a reason for skepticism in the patent litigation context, where the underlying dispute concerns the patentee's claimed legal right to prevent competition.

Second, in negotiating a compromise date of generic entry, the generic manufacturer has a substantial financial incentive to press for the earliest possible entry date, keeping the competitive consequences of the settlement agreement in check. For example, a generic manufacturer that believes it has a strong chance of success typically will not accept a settlement that delays its entry for most of the patent life. See, *e.g.*, Michael J. Meurer, *The Settlement of Patent Litigation*, 20 RAND J. Econ. 77, 77-79 (1989); Carl Shapiro, *Antitrust Analysis of Patent Settlements Between Rivals*, Antitrust, Summer 2003, at 70, 75. The generic manufacturer's desire to maximize its own profits therefore has the practical effect of aligning its interests in paragraph IV litigation with those of consumers, who benefit from the lower prices that generic competition provides. Cf. *Premier Elec. Constr. Co.* v. *National Elec. Contractors Ass'n*, 814 F.2d 358, 369 (7th Cir. 1987) (Easterbrook, J.) ("Th[e] rationale [for approving particular restraints of trade] depends on the alignment of interests between consumers and manufacturers. Destroy that alignment and you destroy the power of the argument."). For that reason, a generic manufacturer's acceptance of a particular deferred entry date provides significant assurance that the agreed-upon date roughly corresponds to the parties' assessments of their likelihood of success in the litigation.

3. Those rationales are inapplicable, however, to settlements that include reverse payments from brand-

name to generic manufacturers. Payments from patentees to accused infringers (or from defendants to plaintiffs more generally) are not a traditional settlement term; to the contrary, they appear to be essentially unknown outside the Hatch-Waxman context. And this Court has never suggested that the bundle of rights a patent provides to its holder includes the right to share the patentee's monopoly profits to induce potential competitors to abandon their efforts to compete or stay out of the market altogether. See *Masonite*, 316 U.S. at 278-282; *United States* v. *Line Material Co.*, 333 U.S. 287, 314-315 (1948); *United States* v. *United States Gypsum Co.*, 333 U.S. 364, 400 (1948); *United States* v. *New Wrinkle, Inc.*, 342 U.S. 371, 378-380 (1952); *United States* v. *Singer Mfg. Co.*, 374 U.S. 174, 196-197 (1963).

Lacking support in the Patent Act and traditional settlement practice, the presence of a reverse payment raises concerns about the integrity of the competition-restricting features of the settlement. The effect of a reverse payment is to sever the alignment of interests that would otherwise exist between the generic manufacturer and consumers when the parties to paragraph IV litigation negotiate a compromise date of generic entry. If the brand-name manufacturer can share its monopoly profits with its potential competitor, both manufacturers will maximize their profits by delaying generic entry, regardless of the parties' assessments of the suit's likely outcome. Where that incentive exists, the generic manufacturer's assent to a particular date of entry provides no assurance that the interests of consumers have been adequately protected in the settlement process. As a leading commentator explains, under a reverse-payment agreement, "the exclusion [of a generic competitor] is a consequence of the payment,

not of the patent itself," and "nothing in the Patent A justifies the exclusion payment." 12 *Antitrust L* ¶ 2046c1, at 347.

One court has nonetheless suggested that rever payment agreements are no different in principle fr the typical settlement because "*any* settlement agr ment can be characterized as involving 'compensation the defendant, who would not settle unless he had so thing to show for the settlement," *Asahi Glass Co Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N Ill. 2003) (Posner, J.), appeal dismissed, 104 Fed. Ap 178 (7th Cir. 2004). That reasoning is faulty. To sure, any settlement that a defendant accepts presu bly affords some benefit that the defendant would receive if it litigated the suit *and lost*. The extrao nary and distinguishing feature of reverse-paym agreements, however, is that the defendant gene manufacturers receive something—a substantial c payment from the brand-name manufacturer that ho a patent—that they could not hope to obtain even if t *prevailed* in the litigation. That feature in turn imp the other terms of the settlement agreement are disc nected from any justification they might otherwise h had in the Patent Act.

C. Reverse-Payment Agreements Frustrate The Purp Of The Hatch-Waxman Amendments

"[A]ntitrust analysis must sensitively recognize reflect the distinctive economic and legal setting of regulated industry to which it applies." *Trinko*, U.S. at 411 (brackets in original) (citation omitted). Hatch-Waxman Amendments reflect a strong congr sional policy that favors testing the scope and validit pharmaceutical patents, with a view to realizing benefits of generic competition at the earliest appro

ate time. See *Pharmaceutical Patent Settlement*, 81 N.Y.U. L. Rev. at 1614 (explaining how reverse-payment agreements undermine the Amendments' careful plan). Reverse-payment agreements frustrate that procompetitive policy by short-circuiting the Amendments' procedures in a way that tends to result in later generic entry than would otherwise occur. See *Pay-for-Delay Report* 2 (finding that Hatch-Waxman settlements with reverse payments were associated with generic entry an average of nearly 17 months later than settlements without). The lead sponsors of the eponymous Hatch-Waxman Amendments have both expressed sharp disapproval of the spread of reverse-payment agreements.[5]

In particular, Congress established the paragraph IV litigation framework to facilitate early and definitive resolution of patent disputes. The Hatch-Waxman Amendments offer substantial incentives both to generic applicants (the 180-day exclusivity period under 21 U.S.C. 355 (j)(5)(B)(iv)) and to brand-name manufacturers (the automatic 30-month stay of FDA approval under 21 U.S.C. 355(j)(5)(B)(iii)) to engage in such litigation. See pp. 5-6, *supra*. Although the Amendments do not compel parties to litigate paragraph IV cases to judgment, nothing in the Amendments contemplates that a patentee will pay an accused infringer in order to escape paragraph IV litigation.

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[5] Senator Orrin Hatch has said that he "f[ou]nd these type of reverse payment collusive arrangements appalling." 148 Cong. Rec. 15,354 (2002). Representative Henry Waxman has explained that "'[t]he law has been turned on its head.' * * * 'We are trying to encourage more generics and through different business arrangements, the reverse has happened.'" Cheryl Gay Stolberg & Jeff Gerth, *How Companies Stall Generics and Keep Themselves Healthy*, N.Y. Times, July 23, 2000, at A1.

The periods of brand-name monopoly pricing that company reverse-payment agreements upset Amendments' "fundamental balance" between innc tion and competition. 130 Cong. Rec. 24,425 (19 (statement of Rep. Waxman); see *House Report* Pt. 2 30 (explaining that the Amendments achieve "what Congress has traditionally done in the area of intelle al property law[:] balance the need to stimulate innc tion against the goal of furthering the public interes see also *K-Dur*, 686 F.3d at 217 ("[I]n passing Hatch-Waxman Act, Congress drew a careful line tween patent protection and the need to provide inc tives for competition in the pharmaceutical industry The Hatch-Waxman Amendments undoubtedly ben generic applicants in some respects, and brand-na manufacturers may well be anxious when paragraph certifications force them into "rolling the dice and ri ing their monopoly profits in * * * patent litigatic Pet. App. 3a. But Congress balanced those feature the Amendments with substantial assurances of prot tion from generic competition for deserving brand-na manufacturers, both through extension of patent ter and through regulatory measures that delay gene manufacturers' opportunity to file or obtain approva an ANDA.[6] Congress's balance would be upset by a ing to these statutory assurances of protection fr competition the opportunity for a brand-name manu

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[6] See, *e.g.*, 35 U.S.C. 156 (extension of patent term); 21 U. 355(j)(5)(D)(ii) (five-year exclusivity for new chemical entity dru 21 U.S.C. 355(j)(5)(D)(iii) (three-year exclusivity for new clir studies); see generally FDA, *Frequently Asked Questions on Pat and Exclusivity* (Dec. 5, 2012), http://www.fda.gov/Dr DevelopmentApprovalProcess/ucm073031.htm.

turer to purchase still more protection by sharing its monopoly profits.

D. Reverse-Payment Agreements Are Appropriately Treated As Presumptively Unlawful Under A "Quick Look" Rule Of Reason Analysis

Although there are abundant reasons to be skeptical of reverse-payment agreements as a class, such agreements should not be treated as categorically unlawful, because per se condemnation would foreclose consideration of possible legitimate justifications for the payment or procompetitive potential that some such agreements may have. See *NCAA* v. *Board of Regents*, 468 U.S. 85, 103-104 (1984) (explaining that per se condemnation is appropriate only if "the likelihood of anticompetitive conduct [is] so great as to render unjustified further examination of the challenged conduct"). Rather, a "so-called 'quick look' or 'truncated rule of reason' analysis" is appropriate because respondents "ha[ve] engaged in practices similar to those subject to per se treatment." *K-Dur*, 686 F.3d at 209 (emphasis omitted). Under that approach, a reverse-payment agreement is presumed to be anticompetitive, and the antitrust defendants bear "the burden of procompetitive justification," *California Dental*, 526 U.S. at 771, by showing, for example, "some countervailing procompetitive virtue" to their agreement, *FTC* v. *Indiana Fed'n of Dentists*, 476 U.S. 447, 459 (1986).

1. "The rule of reason is the accepted standard for testing whether a practice restrains trade in violation of [Sherman Act] § 1." *Leegin Creative Leather Prods., Inc.* v. *PSKS, Inc.*, 551 U.S. 877, 885 (2007). But an "elaborate study of the industry" is not always required. *National Soc'y of Prof'l Eng'rs* v. *United States*, 435 U.S. 679, 692 (1978). "What is required, rather, is an

enquiry meet for the case," *California Dental*, 526 U at 781, arrived at by common-law decision-making, *S Oil Co.* v. *Khan*, 522 U.S. 3, 20-21 (1997). Accordin courts may "establish the litigation structure to ens the rule [of reason] operates to eliminate anticomp tive restraints from the market and to provide m guidance to businesses." *Leegin*, 551 U.S. at 898. S a structure may include rules "for offering proof even presumptions where justified, to make the rul reason a fair and efficient way to prohibit anticomp tive restraints and to promote procompetitive ones." at 898-899.

A presumption of illegality is appropriate und "quick look" rule of reason analysis when "the g likelihood of anticompetitive effects can be easily as tained," *California Dental*, 526 U.S. at 770, or "a cc dent conclusion about the principal tendency of a striction" may be drawn, *id.* at 781. See, *e.g.*, *NC* 468 U.S. at 110 ("[A] naked restraint on price and ou requires some competitive justification even in the sence of a detailed market analysis."); *Indiana Fed' Dentists*, 476 U.S. at 459 (explaining that a restr "imped[ing] the 'ordinary give and take of the ma place'" cannot be sustained "[a]bsent some counter ing procompetitive virtue") (quoting *National Soc' Prof'l Eng'rs*, 435 U.S. at 692).

2. A "quick look" analysis is appropriate here. verse-payment agreements closely resemble o agreements not to compete that this Court has previ ly condemned. They also subordinate the public inte to the agreeing parties' collusive self-interest, in a n ner that is generally devoid of any countervailing vir

"[A]bsent proof of other offsetting consideration, logical to conclude that the *quid pro quo* for [a reve

payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise." *K-Dur*, 686 F.3d at 218 (quoting *In re Schering-Plough Corp.*, 136 F.T.C. 956, 988 (2003), vacated, 402 F.3d 1056 (11th Cir. 2005), cert. denied, 548 U.S. 919 (2006)). As explained above, pp. 20-24, *supra*, such an agreement closely resembles those that this Court has consistently condemned as per se unlawful. Cf. *Polygram Holding, Inc.* v. *FTC*, 416 F.3d 29, 37 (D.C. Cir. 2005) (Ginsburg, C.J.) ("[A] rebuttable presumption of illegality arises * * * from the close family resemblance between the suspect practice and another practice that already stands convicted in the court of consumer welfare.").

Relatedly, a reverse payment reflects the "strong economic self-interest of the parties" to enter into settlements that delay entry. *California Dental*, 526 U.S. at 771 (quoting *United States* v. *Brown Univ.*, 5 F.3d 658, 677 (3d Cir. 1993)); see pp. 21-24, *supra* (discussing the financial motivations behind reverse-payment agreements in general and the agreements here in particular). To be sure, in negotiating any Hatch-Waxman settlement, the brand-name manufacturer will presumably attempt to obtain the longest period of market exclusivity that the perceived strength of its litigating position enables it to achieve. So long as reverse payments are treated as a disfavored settlement term, however, the generic manufacturer can be expected to function as an effective counterweight, seeking to negotiate the earliest possible entry date in order to maximize its own profits. If a settlement without a reverse payment is ultimately consummated, that dynamic provides good reason to presume that consumer interests have been adequately protected in the negotiating

process, and that the period of brand-name monopoly the settlement allows is roughly commensurate with the perceived strength and scope of the relevant patent.

By contrast, when a Hatch-Waxman settlement provides for a substantial reverse payment, the most natural inference is that the payment has purchased an additional increment of market exclusivity. Reverse payments also subordinate the public interests in judicial testing of patent scope and validity, see p. 48, *infra*, and in the integrity of the Hatch-Waxman Amendments' balance between competition and innovation, see pp. 30-33, *supra*. An antitrust court can appropriately treat such agreements as presumptively anticompetitive, particularly since their procompetitive potential is modest, speculative, or achievable by other means (such as a settlement without a reverse payment). See *K-Dur*, 686 F.3d at 218.[7] Such a presumption accords with the weight of legal and economic scholarship.[8]

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[7] Because the agreements challenged in this case involve direct payments of money, this case does not require this Court to address what other consideration would similarly justify a "quick look" analysis. If the economic realities of a settlement coupling an alternative form of consideration with delayed generic entry paralleled those of the direct payments here, such that a court could draw a similarly "confident conclusion about the principal tendency" of those alternative arrangements, *California Dental*, 526 U.S. at 781, then a similar "quick look" analysis would be justified. Cf. *Aggregate Approach to Antitrust*, 109 Colum. L. Rev. at 663-666 (offering possible examples of such arrangements).

[8] See, *e.g.*, Jeremy Bulow, *The Gaming of Pharmaceutical Patents*, in 4 *Innovation Policy and the Economy* 145, 166 (Adam B. Jaffe et al. eds., 2004); Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 Mich. L. Rev. 37, 67-79 (2009); Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, 91 Texas L. Rev. 283, 292 (2012); *Aggregate Approach to Antitrust*, 109 Colum. L. Rev. at 645-670; Herbert

3. If the plaintiff establishes the existence of a reverse-payment agreement, then the burden shifts to the defendants in a rule-of-reason analysis that "focuses directly on the challenged restraint's impact on competitive conditions." *National Soc'y of Prof'l Eng'rs*, 435 U.S. at 688. The parties to the agreement bear the "heavy burden of establishing an affirmative defense which competitively justifies [their agreement's] apparent deviation from the operations of a free market." *NCAA*, 468 U.S. at 113; see *Polygram Holding*, 416 F.3d at 36 (Ginsburg, C.J.) ("[T]o avoid liability, the defendant must either identify some reason the restraint is unlikely to harm competition or identify some competitive benefit that plausibly offsets the apparent anticompetitive harm.").

There are two primary ways in which the parties to a reverse-payment settlement, if later sued for alleged antitrust violations, could rebut the presumption that the agreement is anticompetitive. First, the parties could show that "any money that changed hands was for something other than a delay," *K-Dur*, 686 F.3d at 218, such as the generic manufacturer's provision of property or services unrelated to the brand-name manufacturer's monopoly. Although there is no fixed formula for making that showing, and a court would need to consider the totality of the circumstances surrounding the agreement, relevant considerations would include whether the payment reflected bona fide fair consideration for the property or services; whether other terms of the side transaction comported with industry standards; the existence of previous dealings between the parties on

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Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1759 (2003); Carl Shapiro, *Antitrust Limits to Patent Settlement*, 34 RAND J. Econ. 391, 408 (2003).

the subject matter of the side transaction; a history of demonstrated interest in or need for the property or services on the part of the brand-name manufacturer; and the course and content of the manufacturers' negotiations over the agreements. Sufficient evidence on such subjects could dispel the presumptive inference that the payment secured a delayed entry date.

Second, the defendants in the antitrust suit could rebut the presumption by showing that the payment was commensurate with the litigation costs that the brand-name manufacturer avoided by settling. Because such a payment is most naturally understood to reflect the parties' agreed division of their savings from avoiding litigation, it does not suggest that the compromise date of generic entry specified in the settlement reflects anything but the parties' true assessment of the merits of the litigation. See *Schering-Plough*, 136 F.T.C. at 1000 n.69; Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 Mich. L. Rev. 37, 76-77 (2009) ("A reverse payment that does not exceed [litigation] costs does not present significant concern since the parties would have been required to spend this money in any event.").

In other circumstances (which are likely rare), certain unusual business or litigation justifications may also supply a rebuttal. For example, the Third Circuit noted that "a modest cash payment that enables a cash starved generic manufacturer to avoid bankruptcy and begin marketing a generic drug might have an overall effect of increasing the amount of competition in the market." *K-Dur*, 686 F.3d at 218. Lower courts have had little opportunity to explore the other possible "countervailing procompetitive virtue[s]," *Indiana Fed'n of Dentists*, 476 U.S. at 459, to particular settle

ments, but in general defendants should be fully heard on each of their "proffered justifications," *NCAA*, 468 U.S. at 113. The evidence supporting any of those rebuttals is likely to be uniquely in the possession of the parties to the reverse-payment agreement. The defendants' superior access to evidence of any procompetitive tendencies of their agreement is a further reason to favor the burden-shifting approach of a "quick look" analysis. See, *e.g.*, 2 Kenneth S. Broun et al., *McCormick on Evidence* § 343, at 500 (6th ed. 2006).

4. The "fundamental goal of antitrust law" is to enhance consumer welfare by increasing output and decreasing the price of goods and services. *NCAA*, 468 U.S. at 107; cf. Robert H. Bork, *The Antitrust Paradox: A Policy at War with Itself* 67 (1978) ("The per se rule against naked price fixing and similar agreements not to compete * * * can be explained only by a preference for consumer welfare as the exclusive goal of antitrust."). Antitrust law seeks to achieve that goal, however, not by inducing business entities to behave altruistically, but by channeling companies' pursuit of their own self-interest into conduct that is likely to benefit consumers. See *Premier Elec.*, 841 F.2d at 369-370 (Easterbrook, J.). If the governing legal regime treated payments not to compete as a legitimate means of earning income, firms could not be faulted for accepting (or making) such payments when doing so appeared likely to maximize company profits. By proscribing such arrangements, antitrust law seeks to benefit consumers by making actual competition in the marketplace the profit-maximizing course of conduct.

Similarly here, a rule treating reverse payments as presumptively unlawful will preserve incentives for brand-name and generic manufacturers to resolve para-

graph IV litigation in alternative ways that do not undo the manufacturers' competitive relationship. Most obviously, the parties may settle with an earlier entry date and no reverse payment, which would benefit consumers by lengthening the period during which price competition could occur. That is by far the most common type of settlement of paragraph IV litigation. See FTC, *Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act* 2 (FY 2012), http://www.ftc.gov/os/2013/01/130117mmareport.pdf (*2012 MMA Report*).

To be sure, in some paragraph IV litigation that might otherwise have been settled through reverse-payment agreements, a rule discountenancing reverse payments may cause the parties to litigate to judgment. But in the aggregate, those judgments on the merits will reflect results more in keeping with the policies of the antitrust laws, the Patent Act, and the Hatch-Waxman Amendments than if all the cases had been settled with reverse payments. The judgments in such cases will reflect determinations by judges or juries, based on adversary presentations by the brand-name and generic manufacturers, as to the *actual* exclusionary force of the relevant patents. By contrast, the presumptive purpose of a reverse payment is to compensate the generic manufacturer for accepting an entry date later than the parties' assessments of the merits (and thus of their own bargaining power) would otherwise have produced.

II. THE "QUICK LOOK" APPROACH, UNDER WHICH REVERSE-PAYMENT AGREEMENTS ARE TREATED AS PRESUMPTIVELY UNLAWFUL, IS SUPERIOR TO THE TWO PRINCIPAL ALTERNATVE MODES OF ANALYSIS

The case law has identified two principal alternatives to the "quick look" approach described above and adopt-

ed by the Third Circuit in *K-Dur*. First, the court below held that "absent sham [patent] litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." Pet. App. 28a. The Second and Federal Circuits have also adopted that legal standard, which is commonly known as the scope-of-the-patent approach. See *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 212-213 (2d Cir. 2006), cert. denied, 551 U.S. 1144 (2007); *In re Ciprofloxacin Hydrochloride Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008), cert. denied, 557 U.S. 920 (2009) (*Cipro*). Second, it has been suggested that antitrust analysis of a reverse-payment agreement should focus on "the strength of the patent as it appeared at the time at which the parties settled." *Tamoxifen*, 466 F.3d at 228 (Pooler, J., dissenting). The "quick look" approach is superior to both of those alternatives.[9]

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[9] The view that reverse-payment agreements are presumptively unlawful is the longstanding position of the FTC, and it has been the position of the United States in recent briefs filed in the Second and Third Circuits. See U.S. Amicus Br., *K-Dur*, *supra* (No. 10-2077) (filed May 18, 2011); U.S. Amicus Br., *Arkansas Carpenters Health & Welfare Fund* v. *Bayer AG*, 604 F.3d 98 (2d Cir. 2010) (No. 05-2851) (filed July 7, 2009, at court's invitation); U.S. Amicus Br., *Arkansas Carpenters*, *supra* (No. 05-2851) (filed June 4, 2010, on petition for rehearing). In three prior cases, in response to invitations from this Court, the United States has filed petition-stage briefs discussing the proper treatment of such agreements. See *Andrx Pharms., Inc.* v. *Kroger Co.*, 540 U.S. 1160 (2004) (Court invitation); *FTC* v. *Schering-Plough Corp.*, 546 U.S. 974 (2006) (same); *Joblove* v. *Barr Labs., Inc.*, 549 U.S. 1277 (2007) (same). In those briefs, the United States did not endorse the FTC's view that reverse-payment settlements are presumptively anticompetitive. The United States did contend, however, that the scope-of-the patent approach is an "insufficiently

A. The Scope-Of-The-Patent Approach Inappropriatel Insulates Reverse-Payment Agreements From Meaning ful Antitrust Scrutiny

Courts endorsing the scope-of-the-patent approac have concluded that, because the core right conferred b a patent is the right to exclude competition, a reverse payment agreement is not *unlawfully* anticompetitive s long as it permits generic entry on or before the dat when the patent is scheduled to expire. See, *e.g.*, Pe App. 23a-24a; *Tamoxifen*, 466 F.3d at 201-202, 213-21 *Valley Drug Co.* v. *Geneva Pharms., Inc.*, 344 F.3d 129 1304-1306 (11th Cir. 2003), cert. denied, 543 U.S. 99 (2004). In effect, those courts assess (and discount) th anticompetitive potential of a reverse-payment agree ment by comparing the level of generic competition i permits to the level of competition that would have oc curred if the infringement suit had been litigated t judgment and the patentee had prevailed. Use of tha forgiving baseline is contrary to basic competition-la

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stringent standard" for determining the propriety of those settl ments. U.S. Br. at 8, *Joblove* v. *Barr Labs., Inc.*, 551 U.S. 1144 (200 (No. 06-830); see *id.* at 12-15. The United States argued, albe without advocating any specific test, that the antitrust inquiry shou include an assessment of the likelihood that the brand-name manu facturer would have prevailed in the underlying infringement sui See *id.* at 12 ("In determining whether the exclusionary effect of settlement involving a reverse payment renders the settlemen unreasonable and anticompetitive, a court at a minimum should tak into account the relative likelihood of success of the parties' claim viewed ex ante."); U.S. Br. at 11, *FTC* v. *Schering-Plough Corp.*, 5 U.S. 919 (2006) (No. 05-273). This Court denied certiorari in all thr cases. See *Andrx Pharms., Inc.* v. *Kroger Co.*, 543 U.S. 939 (2004 *Schering-Plough*, *supra*; *Joblove*, *supra*.

principles; it derives no support from the Patent Act; and it disserves consumer welfare.[10]

1. As explained above (see pp. 20-21, *supra*), a potential competitor's agreement to forgo market entry in exchange for a payment is ordinarily unlawful per se, even if the prospect of entry was uncertain to begin with. Parties to such an agreement cannot avoid antitrust liability simply by demonstrating that other forces might have produced the same result. The fact that a potential generic competitor *might* have been excluded from the market if the infringement suit had been litigated to judgment therefore does not mean that the same result can lawfully be achieved through an agreement between competitors.

2. Nothing in the Patent Act suggests that, in determining the appropriate baseline against which the anticompetitive potential of a reverse-payment agreement will be measured, the antitrust court should assume that the relevant patent is valid and infringed. Reverse-payment agreements in Hatch-Waxman cases serve by definition to settle litigation whose outcome is uncertain. The parties to any such agreement, moreover, include both the generic manufacturer, who has submitted a

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[10] The reverse-payment agreements at issue here allow generic entry on August 31, 2015, five years before the relevant patent will expire. See Pet. App. 10a, 12a. The agreement thus contemplated a greater degree of generic competition than might have occurred if the case had been litigated to judgment and the patentee (Solvay) had prevailed. Under the scope-of-the-patent approach, however, that fact is irrelevant to the antitrust inquiry. Rather, because that approach effectively condemns only agreements that limit generic competition *more severely* than would a court judgment in the patentee's favor, it would treat the agreement here as no less lawful if the generic manufacturers had agreed to defer competition until the date of patent expiration.

paragraph IV certification stating that the patent is invalid or that its own product will not be infringing, and the brand-name manufacturer, who has responded to the paragraph IV certification by initiating an infringement action.

Given the uncertainty as to the outcome of the infringement suit, and the contracting parties' divergent positions on the merits of that litigation, it would be unsound to assume for antitrust purposes that one party to the reverse-payment agreement was right and the other was wrong. Moreover, because the scope-of-the-patent approach assumes (at least once the non-sham threshold has been surmounted) that all patents are equally valid and infringed, it "produces the absurd result that an ironclad patent and a trivial patent have the same exclusionary force." *Aggregate Approach to Antitrust*, 109 Colum. L. Rev. at 638. Thus, the scope-of-the-patent approach allows the patentee to purchase the same period of exclusivity that a successful infringement suit would produce, even if all would concede that the patentee had little likelihood of prevailing in the infringement litigation. See *Tamoxifen*, 466 F.3d at 211 (expressing concern about the "troubling dynamic" that "the patents most likely to be the subject of exclusion payments would be precisely those patents that have the most questionable validity") (citation omitted).

3. The scope-of-the-patent approach, which effectively assumes for antitrust purposes that the relevant patent is valid and infringed, likewise finds no support in the available empirical evidence concerning actual outcomes in litigated patent cases. Both in the Hatch-Waxman context and more generally, accused infringers have prevailed in a substantial percentage of such lawsuits. See pp. 6-7, *supra*. Consumers have reaped

enormous benefits from the intense competition—in both the marketplace and the courtroom—between brand-name and generic manufacturers. When the brand-name manufacturer holds a strong patent, it is likely to prevail in litigation and to prevent or significantly delay generic entry—as it should, in order to preserve the incentives to innovate that benefit consumers in the long run. Yet generic manufacturers have fulfilled the promise of the Hatch-Waxman Amendments by repeatedly succeeding in inventing around narrow drug patents and invalidating others, bringing competition to the marketplace years before the patents would have expired and saving consumers billions of dollars. See, *e.g.*, *Generic Pharmaceuticals: Marketplace Access and Consumer Issues: Hearing Before the Senate Comm. on Commerce, Science & Transportation*, 107th Cong., 2d Sess. 61 (2002) (Statement of Kathleen D. Jaeger, President & CEO, Generic Pharm. Ass'n) (estimating successful challenges to patents related to the widely used drugs Prozac, Zantac, Taxol, and Platinol alone as saving consumers more than $9 billion).

If this Court were to adopt the scope-of-the-patent approach as the applicable nationwide rule, brand-name manufacturers would have little reason *not* to offer their potential generic competitors payments not to compete, and the generic manufacturers would have little reason to refuse. Consumers would then bear the costs of the increased frequency and severity of reverse-payment agreements. Such agreements are demonstrably associated with delayed entry of generic competition, costing consumers billions of dollars each year. See *Pay-for-Delay Report* 2. A large fraction of the drug market would be susceptible to the influence of such agreements: At the end of Fiscal Year 2008, an estimated $90

billion of brand-name drug sales were under threat fron one or more ANDAs containing a paragraph IV certifi cation. See *id.* at 9. This Court's adoption of the scope of-the-patent approach would likely embolden manufac turers to enter into more such agreements, on mor harmful terms.

B. The Scope-Of-The-Patent Approach Relies On A Uncritical Acceptance Of The Benefits Of Settlement I General, And Of The Necessity Of Reverse Payments I Particular

Some courts have found the scope-of-the-patent ap proach to be justified by the general public policy favor ing voluntary settlement of litigation. See, *e.g.*, *Cipr* 544 F.3d at 1333; *Tamoxifen*, 466 F.3d at 202-203; *Val ley Drug*, 344 F.3d at 1308. Although settlements o litigation often further the public interest and benefi consumers, the scope-of-the-patent approach mistakenl assumes both that Hatch-Waxman settlements are al ways in the public interest and that reverse payment are a necessary component of such settlements.

1. The "quick look" approach that we advocate nei ther precludes nor treats as presumptively unlawful al voluntary settlements of patent-infringement suits be tween brand-name and generic drug manufacturers. T the contrary, if the "quick look" approach is adopted, th parties to Hatch-Waxman suits will retain broad latitud to avoid the burdens and uncertainty of litigation b agreeing on a compromise date of generic entry. Onl those settlements that involve a reverse payment (or it functional equivalent) from the plaintiff to the defendan would be presumed anticompetitive. See pp. 34-36 & note 7, *supra*; *K-Dur*, 686 F.3d at 218. Such payment are scarcely an essential or traditional feature of settle ment practice, and they raise distinct threats to con

sumer interests, since the natural effect of a reverse payment is to dilute the generic manufacturer's usual incentive to negotiate for the earliest achievable entry date. See *Aggregate Approach to Antitrust*, 109 Colum. L. Rev. at 666, 668-669; p. 28, *supra*.

Even in the Hatch-Waxman setting, reverse payments are not necessary to achieve settlements. In the early 2000s, before any court had adopted the scope-of-the-patent approach, it appears that manufacturers regularly settled paragraph IV litigation without reverse payments. In 2012, more than 70% of Hatch-Waxman settlements did *not* involve the brand-name manufacturer compensating the generic manufacturer and the generic manufacturer agreeing to delay entry. *2012 MMA Report* 2. Adopting the "quick look" approach therefore "w[ould] leave the vast majority of pharmaceutical patent settlements unaffected." *K-Dur*, 686 F.3d at 218.

2. In any event, the public policy favoring settlement of litigation does not invariably "displace countervailing public policy objectives." *K-Dur*, 686 F.3d at 217. "While public policy wisely encourages settlements," some settlements can impose "too high a price." *McDermott, Inc.* v. *AmClyde*, 511 U.S. 202, 215 (1994); cf. *United States* v. *Reliable Transfer Co.*, 421 U.S. 397, 408 (1975) ("Congestion in the courts cannot justify a legal rule that produces unjust results in litigation simply to encourage speedy out-of-court accommodations.").

Competition law itself embodies some of those countervailing objectives. Two parties to an ordinary commercial dispute might be willing to put their differences aside if they could enjoy the rewards of a price-fixing conspiracy. But the mere fact that such an agreement was memorialized in a litigation settlement would not

exonerate it. See, *e.g.*, 12 *Antitrust Law* ¶ 2046c1, a 342-343 ("[W]e would not permit parties to settle a ordinary breach of contract dispute by an agreemen fixing their prices or dividing their markets.").

Another countervailing objective is the public benefi from judicial testing of patent scope and elimination o invalid patents. "A patent by its very nature is affecte with a public interest. * * * The far-reaching socia consequences of a patent, therefore, give the public paramount interest in seeing that patent monopolie * * * are kept within their legitimate scope." *Preci sion Instrument Mfg. Co.* v. *Automotive Maint. Mach Co.*, 324 U.S. 806, 816 (1945). "It is as important to th public that competition should not be repressed b worthless patents, as that the patentee of a really valua ble invention should be protected in his monopoly. *Pope Mfg. Co.* v. *Gormully*, 144 U.S. 224, 234 (1892); se *Cardinal Chem. Co.* v. *Morton Int'l, Inc.*, 508 U.S. 8 100-101 (1989); see also pp. 30-33, *supra* (discussin strong congressional policy in Hatch-Waxman Amend ments favoring testing the scope and validity of pharma ceutical patents).

Still another countervailing consideration is the stee price consumers would pay (in comparison to the pa ties' relatively modest savings from settlement) unde the scope-of-the-patent approach. See C. Scot Hemphill & Mark A. Lemley, *Earning Exclusivity Generic Drug Incentives and the Hatch-Waxman Ac* 77 Antitrust L.J. 947, 980 (2011) ("[L]itigation costs ar dwarfed by the magnitude of the stakes at issue in thes cases."); *Aggregate Approach to Antitrust*, 109 Colu L. Rev. at 649-650 & n.85 (estimating a one-year delay i generic entry resulted in an average harm to consumer of at least $661 million per drug product); Am. Intelle

tual Prop. Law Ass'n, *Report of the Economic Survey 2011*, at 35-36 (finding that patent litigation costs rarely exceed $10 million).

C. The Economic Incentives Created By The Hatch-Waxman Amendments Do Not Justify The Scope-Of-The-Patent Approach

Reverse-payment agreements bypass the Hatch-Waxman Amendments' framework for resolving patent disputes in a way that upsets the Amendments' balance between innovation and competition. See pp. 30-33, *supra*. Courts that have adopted the scope-of-the-patent approach have nonetheless invoked the Amendments as a purported source of support, characterizing reverse-payment agreements as a natural response to the incentives that the Amendments create. That reasoning is faulty.

1. The particular risks to brand-name manufacturers from Hatch-Waxman litigation do not excuse anti-competitive conduct by those manufacturers

Courts favoring the scope-of-the-patent approach have expressed the view that "reverse payments are particularly to be expected in the drug-patent context because the Hatch-Waxman [Amendments] created an environment that encourages them." *Tamoxifen*, 466 F.3d at 206; see *Schering-Plough Corp.* v. *FTC*, 402 F.3d 1056, 1074 (11th Cir. 2005), cert. denied, 548 U.S. 919 (2006). Those courts have reasoned that, because paragraph IV litigation typically occurs before the generic manufacturer has made commercial sales, the generic manufacturer has minimal exposure to a damages award, eliminating one subject of compromise that is often available in patent-infringement suits. See *Tamoxifen*, 466 F.3d at 206-207; *Schering-Plough*, 402

F.3d at 1074-1075. That aspect of the Hatch-Waxmar Amendments provides no justification for the scope-of the-patent approach.

First, the absence of a damages claim in paragrapl IV litigation does not put brand-name manufacturers ir a position substantially different from what other pa tentees might face. The Declaratory Judgment Ac (DJA), 28 U.S.C. 2201, is available to a potential infring er who establishes a "real and substantial" and "definit and concrete" dispute with a patentee. *Aetna Life Ins Co.* v. *Haworth*, 300 U.S. 227, 240-241 (1937). In som cases, that standard may be satisfied even though th DJA plaintiff has not yet engaged in conduct that coul subject it to damages liability. See *Medimmune, Inc.* v *Genentech, Inc.*, 549 U.S. 118, 126-134 (2007). Outsid the Hatch-Waxman context, however, reverse payment have not been used (at least with any meaningful fre quency) to settle declaratory judgment actions challeng ing the validity of patents.

Second, if a brand-name manufacturer faces unusual ly strong pressure to settle a particular Hatch-Waxma suit (either because its likelihood of prevailing is unusu ally low or because the costs of defeat would be unusual ly high), the generic challenger can exploit that pressur in either of two ways. The generic manufacturer ca seek to negotiate the earliest possible date of generi entry, thereby maximizing its own ability to compete i the relevant market. Alternatively, the generic manu facturer can demand a substantial monetary payment i exchange for agreeing to a later entry date. So long a the agreed-upon entry date is no later than the date o patent expiration, the scope-of-the-patent approac treats those two responses as equally legitimate mean of exploiting the generic manufacturer's bargainin

power. Collusion between competitors, however, has traditionally been viewed as "the supreme evil of antitrust." *Trinko*, 540 U.S. at 408. As between the two negotiating tactics described above, requiring the generic manufacturer to pursue the course that maximizes competition and consumer welfare accords with basic antitrust norms. See pp. 39-40, *supra*.

Third, the existence of financial motives for reverse-payment agreements is ultimately beside the point. The competition laws exist precisely to counteract commercial "environment[s] that encourage[]," *Tamoxifen*, 466 F.3d at 206, collusive and anticompetitive behavior. Observations about the opportunities and incentives for anticompetitive behavior that the Hatch-Waxman Amendments may create no more justify reverse-payment agreements than "the age-old cry of ruinous competition and competitive evils [is] a defense to price-fixing conspiracies," *Socony-Vacuum*, 310 U.S. at 221; see *Masonite*, 316 U.S. at 276 ("Since there was price-fixing, the fact that there were business reasons which made the arrangements desirable to the [antitrust defendants] * * * would be no more a legal justification for price-fixing than were the 'competitive evils' in the *Socony-Vacuum* case."). Firms agree to restrain trade precisely because it is in their economic self-interest, and the antitrust laws condemn such restraints because they are socially harmful.

2. The possibility that other generic manufacturers will challenge the brand-name manufacturer's monopoly does not support the scope-of-the-patent approach

The court below expressed the views that "there usually are many potential challengers to a patent, at least to drug patents," and that "[i]f the patent actually is vulnerable, then presumably other generic companies

* * * will attempt to enter the market and make their own challenges to the patent." Pet. App. 35a-36a. That reasoning is unsound.

In general, the threat of subsequent generic competition is unlikely to mitigate concerns about a reverse-payment agreement with the first generic applicant. As the Third Circuit explained, "the initial challenger is necessarily the most motivated because, unlike all subsequent challengers, it stands to benefit from the 180-day exclusivity period of 21 U.S.C. § 355(j)(5)(B)(iv)." *K-Dur*, 686 F.3d at 215; see Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition* 39 U.S.F. L. Rev. 11, 25-26 (2004). A subsequent generic applicant's entry can be delayed for a much lower price because a later applicant has much less to gain if it submits a paragraph IV certification and ultimately prevails in court. That is so not only because a successful second or later filer is not awarded a period of exclusivity, but also because it is likely to face competition from generic manufacturers who previously settled litigation. See Complaint ¶¶ 65, 76, J.A. 46, 49 (alleging that the settlements here, like typical Hatch-Waxman settlements, permit the settling generic manufacturer to enter the market immediately if a third-party prevails in patent litigation against the brand-name manufacturer).

Experience bears out this analysis: When multiple generic manufacturers have found it worthwhile to make paragraph IV certifications, brand-name manufacturers have often responded by simply making reverse payments to each generic competitor. See *2012 MMA Report* 1 (reporting 26 drug products associated with more than one reverse-payment agreement, and 14 drug products associated with at least three reverse-payment agreements).

D. The "Quick Look" Approach Is Preferable To An Alternative That Requires The Antitrust Court To Assess The Likely Outcome Of The Underlying Infringement Suit

A second alternative to the "quick look" approach is to compare the level of competition that a particular reverse-payment settlement allows to the likelihood that the patent holder would have prevailed in the underlying infringement suit. Under that mode of analysis, the antitrust court would assess the relative strength of the brand-name and generic manufacturers' competing arguments, as of the time of settlement, with respect to contested issues of patent validity and infringement. That approach would afford greater protection to consumer interests than does the scope-of-the-patent rule. This alternative is inferior to the "quick look" approach, however, because it is doctrinally anomalous and likely unworkable in practice.

Under usual antitrust principles, a collusive effort by firms to avoid competing is forbidden even if the prospect of competition was already uncertain. "[Competition] law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition." 12 *Antitrust Law* ¶ 2030b, at 220; see pp. 20-21, *supra*. An agreement to divide markets or to fix prices can ordinarily be condemned as per se unlawful, without regard to the likelihood that actual competition would have occurred, or that the prices charged would have been different, in the absence of the agreement. Cf. 3 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 657a2, at 162 (3d ed. 2008) ("[T]he government suitor need not show that competition is in fact less than it would be in some alternative universe in which the challenged conduct had not occurred. It is enough to show that anticompetitive

consequences are a naturally-to-be-expected outcome of the challenged conduct."). If a reverse-payment settlement is functionally comparable to the sorts of agreements that have previously received per se condemnation, it would be anomalous to hold the agreement lawful based on an after-the-fact determination that the patent holder's position in the infringement suit was particularly strong. By the same token, a Hatch-Waxman settlement that does not include any reverse payment (or its functional equivalent), but simply provides for a compromise date of generic entry, should ordinarily raise no antitrust concern, regardless of the perceived likelihood that the patent holder would have prevailed if the suit had been litigated to judgment.

Administrative concerns also strongly disfavor an approach that would tie the lawfulness of the manufacturers' agreement to a comparison with the projected outcome of the paragraph IV litigation. Many courts (including the one below) have recognized the disadvantages of effectively retrying the patent case inside the subsequent antitrust action. See Pet. App. 36a (describing the prospect of "deciding a patent case within an antitrust case about the settlement of the patent case" as an "[un]palatable" "turducken task"). Among those disadvantages are the powerful disincentive to settlement it creates (because the manufacturers know they may be forced by an antitrust plaintiff to effectively litigate the patent-infringement suit anyway) and the troublesome realignment of the generic manufacturer's interests it produces (because the generic manufacturer will argue in the subsequent antitrust suit that it had no hope of prevailing in patent litigation it had previously triggered through its own paragraph IV certification). The "quick look" approach avoids an inappropriate and

cumbersome retrial of the patent case by asking whether, in avoiding the risks that accompany patent infringement litigation, the parties have by contract obtained more exclusion than warranted in light of those risks.[11]

III. THE FTC'S COMPLAINT STATES A CLAIM UPON WHICH RELIEF CAN BE GRANTED

The FTC's complaint in this case states a claim under a "quick look" approach that treats reverse-payment agreements as presumptively unlawful. It alleges that Solvay is the seller of AndroGel® and was issued a patent that (Solvay contended) claimed the drug's formulation. Complaint ¶¶ 16, 31, 39-42, J.A. 32, 36, 38-39. The complaint further alleges that Watson and Par/Paddock are generic drug manufacturers that filed ANDAs with FDA seeking approval to market generic versions of AndroGel®, and that they made paragraph IV certifications to Solvay's patent, asserting that their products did not infringe Solvay's patent and that the patent was invalid. *Id.* ¶¶ 13-15, 44, 46, J.A. 31, 39-40. The complaint explains that entry by Watson and Par/Paddock would have substantially reduced Solvay's sales of AndroGel® and would have saved consumers hundreds

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[11] Quantification of damages in a private antitrust action might require an assessment of what sequence of events would likely have ensued in the absence of a reverse payment. Cf. *Atlantic Richfield Co.* v. *USA Petroleum Co.*, 495 U.S. 328, 341-342 (1990) ("The *per se* rule is a method of determining whether [Section] 1 of the Sherman Act has been violated, but it does not indicate whether a private plaintiff has suffered antitrust injury and thus whether he may recover damages."). That issue is not presented here because the FTC seeks only declaratory and prospective injunctive relief. See Pet. 31.

of millions of dollars a year. *Id.* ¶¶ 49-50, 58, 98, J.A. 41, 43, 57-58.

The complaint alleges that Solvay filed patent infringement actions against the generic challengers, which the parties later agreed to settle. Complaint ¶¶ 47, 65, 76, J.A. 40, 46, 49. In particular, Watson, Par, and Paddock agreed to refrain from marketing generic AndroGel® for nine years, until August 31, 2015. *Id.* ¶¶ 65, 76, J.A. 46, 49. Solvay agreed to make payments to Watson (starting at approximately $19 million during the first year of their agreement in 2006 and rising to more than $30 million annually by 2015), to Par (of $10 million annually), and to Paddock (of $2 million annually). *Id.* ¶ 66, 73-74, J.A. 46, 48. The agreements also stated that the generic manufacturers would provide certain services in support of Solvay's manufacturing and marketing of AndroGel®. See *id.* ¶¶ 66, 77, J.A. 46, 49. "By deferring competition, the parties would preserve monopoly profits that could be shared amongst them—at the expense of the consumer savings that would result from price competition." *Id.* ¶ 58, J.A. 43.

CONCLUSION

The judgment of the court of appeals should be reversed and the case remanded for further proceedings.

Respectfully submitted.

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APPENDIX

1. 15 U.S.C. 1 provides in relevant part:

Trusts, etc., in restraint of trade illegal; penalty

Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. * * *

2. 15 U.S.C. 2 provides in relevant part:

Monopolizing trade a felony; penalty

Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, * * * .

3. 15 U.S.C. 45(a)(1)-(2) provides:

Unfair methods of competition unlawful; prevention by Commission

(a) Declaration of unlawfulness; power to prohibit unfair practices; inapplicability to foreign trade

(1) Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.

(2) The Commission is hereby empowered and directed to prevent persons, partnerships, or corporations * * * from using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce.

4. 15 U.S.C. 53(b) provides:

False advertisements; injunctions and restraining orders

* * * * *

(b) Temporary restraining orders; preliminary injunctions

Whenever the Commission has reason to believe—

(1) that any person, partnership, or corporation is violating, or is about to violate, any provision of law enforced by the Federal Trade Commission, and

(2) that the enjoining thereof pending the issuance of a complaint by the Commission and until such complaint is dismissed by the Commission or set aside by the court on review, or until the order of the Commission made, thereon has become final, would be in the interest of the public—

the Commission by any of its attorneys designated by it for such purpose may bring suit in a district court of the United States to enjoin any such act or practice.

Upon a proper showing that, weighing the equities and considering the Commission's likelihood of ultimate success, such action would be in the public interest, and after notice to the defendant, a temporary restraining order or a preliminary injunction may be granted without bond: *Provided, however*, That if a complaint is not filed within such period (not exceeding 20 days) as may be specified by the court after issuance of the temporary restraining order or preliminary injunction, the order or injunction shall be dissolved by the court and be of no further force and effect: *Provided further*, That in proper cases the Commission may seek, and after proper proof, the court may issue, a permanent injunction. Any suit may be brought where such person, partnership, or corporation resides or transacts business, or wherever venue is proper under section 1391 of title 28. In addition, the court may, if the court determines that the interests of justice require that any other person, partnership, or corporation should be a party in such suit, cause such other person, partnership, or corporation to be added as a party without regard to whether venue is otherwise proper in the district in which the suit is brought. In any suit under this section, process may be served on any person, partnership, or corporation wherever it may be found.

* * * * *

5. 21 U.S.C. 355(j) (2006 & Supp. V 2011) provides:

New drugs

* * * * *

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval

of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 321(p) of this title, and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the

listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (B) through (F) of subsection (b)(1) of this section;

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

(i) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) TIMING OF NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at

which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(iii) RECIPIENTS OF NOTICE.—An applicant required under this subparagraph to give notice shall give notice to—

(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(II) the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(iv) CONTENTS OF NOTICE.—A notice required under this subparagraph shall—

(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds—

(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(D)(i) An applicant may not amend or supplement an application to seek approval of a drug referring to a different listed drug from the listed drug identified in the application as submitted to the Secretary.

(ii) With respect to the drug for which an application is submitted, nothing in this subsection prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(iii) Within 60 days after December 8, 2003, the Secretary shall issue guidance defining the term "listed drug" for purposes of this subparagraph.

(3)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached

between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).

(4) Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds—

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed

drug, information submitted with the application is insufficient to show—

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 321(p) of this title,

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended,

or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of this section of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section, the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) of this section for grounds described in the first sentence of subsection (e) of this section, the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (6), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); or

(K) the application contains an untrue statement of material fact.

(5)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) of this section before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such

shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed—

(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(iv) 180-DAY EXCLUSIVITY PERIOD.—

(I) EFFECTIVENESS OF APPLICATION.—Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

(II) DEFINITIONS.—In this paragraph:

(aa) 180-DAY EXCLUSIVITY PERIOD.—The term "180-day exclusivity period" means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) FIRST APPLICANT.—As used in this subsection, the term "first applicant" means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) SUBSTANTIALLY COMPLETE APPLICATION.—As used in this subsection, the term "substantially complete application" means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) TENTATIVE APPROVAL.—

(AA) IN GENERAL.—The term "tentative approval" means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or section 355a of this title, or there is a 7-year period of exclusivity for the listed drug under section 360cc of this title.

(BB) LIMITATION.—A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(C) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—

(I) IN GENERAL.—No action may be brought under section 2201 of title 28 by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) FILING OF CIVIL ACTION.—If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in

accordance with section 2201 of title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) OFFER OF CONFIDENTIAL ACCESS TO APPLICATION.—For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the

purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

(I) IN GENERAL.—If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringe-

ment action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) NO INDEPENDENT CAUSE OF ACTION.—Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(D) FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.—

(i) DEFINITION OF FORFEITURE EVENT.—In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:

(I) FAILURE TO MARKET.—The first applicant fails to market the drug by the later of—

(aa) the earlier of the date that is—

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement

order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) of this section is withdrawn by the holder of the application approved under subsection (b) of this section.

(II) WITHDRAWAL OF APPLICATION.—The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(III) AMENDMENT OF CERTIFICATION.—The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) FAILURE TO OBTAIN TENTATIVE APPROVAL.—The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) AGREEMENT WITH ANOTHER APPLICANT, THE LISTED DRUG APPLICATION HOLDER, OR A PATENT OWNER.—The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of title 15, except that the term includes section 45 of title 15 to the extent that that section applies to unfair methods of competition).

(VI) EXPIRATION OF ALL PATENTS.—All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) FORFEITURE.—The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(iii) SUBSEQUENT APPLICANT.—If all first applicants forfeit the 180-day exclusivity period under clause (ii)—

(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

(II) no applicant shall be eligible for a 180-day exclusivity period.

(E) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(F)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the

expiration of ten years from the date of the approval of the application under subsection (b) of this section.

(ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) of this section for a drug, which includes an active

ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section for such drug.

(iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) of this section.

(v) If an application (or supplement to an application) submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been

approved in another application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from September 24, 1984.

(6) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—

(A) for the same period as the withdrawal or suspension under subsection (e) of this section or this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(7)(A)(i) Within sixty days of September 24, 1984, the Secretary shall publish and make available to the public—

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) of this section before September 24, 1984;

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) of this section or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (b) or (c) of this section respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(B) A drug approved for safety and effectiveness under subsection (c) of this section or approved under this subsection shall, for purposes of this subsection,

be considered to have been published under subparagraph (A) on the date of its approval or September 24, 1984, whichever is later.

(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under paragraph (6) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

(i) for the same period as the withdrawal or suspension under subsection (e) of this section or paragraph (6), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(8) For purposes of this subsection:

(A)(i) The term "bioavailability" means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

(ii) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may assess bioavailability by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of drug action.

(B) A drug shall be considered to be bioequivalent to a listed drug if—

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

(C) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may es-

tablish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.

(9) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of—

(A) the name of the applicant,

(B) the name of the drug covered by the application,

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment.

The information the Secretary is required to maintain under this paragraph with respect to an application submitted under this subsection shall be made available to the public after the approval of such application.

(10)(A) If the proposed labeling of a drug that is the subject of an application under this subsection differs from the listed drug due to a labeling revision described under clause (i), the drug that is the subject of such application shall, notwithstanding any other provision of this chapter, be eligible for approval and

shall not be considered misbranded under section 352 of this title if—

(i) the application is otherwise eligible for approval under this subsection but for expiration of patent, an exclusivity period, or of a delay in approval described in paragraph (5)(B)(iii), and a revision to the labeling of the listed drug has been approved by the Secretary within 60 days of such expiration;

(ii) the labeling revision described under clause (i) does not include a change to the "Warnings" section of the labeling;

(iii) the sponsor of the application under this subsection agrees to submit revised labeling of the drug that is the subject of such application not later than 60 days after the notification of any changes to such labeling required by the Secretary; and

(iv) such application otherwise meets the applicable requirements for approval under this subsection.

(B) If, after a labeling revision described in subparagraph (A)(i), the Secretary determines that the continued presence in interstate commerce of the labeling of the listed drug (as in effect before the revision described in subparagraph (A)(i)) adversely impacts the safe use of the drug, no application under this subsection shall be eligible for approval with such labeling.

6. 21 U.S.C. 355(j) (2000) provided:

New drugs

* * * * *

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), infor-

mation to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 321(p) of this title, and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the

listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (B) through (F) of subsection (b)(1) of this section;

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B)(i) An applicant who makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give the notice required by clause (ii) to—

(I) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

(II) the holder of the approved application under subsection (b) of this section for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

(ii) The notice referred to in clause (i) shall state that an application, which contains data from bioavailability or bioequivalence studies, has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of such drug before the expiration of the patent referred

to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

(iii) If an application is amended to include a certification described in subparagraph (A)(vii)(IV), the notice required by clause (ii) shall be given when the amended application is submitted.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds—

(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(3)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).

(4) Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds—

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show—

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 321(p) of this title,

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or

the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of this section of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section, the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) of this section for grounds described in the first sentence of subsection (e) of this section, the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (6), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); or

(K) the application contains an untrue statement of material fact.

(5)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined under the following:

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision,

(II) if before the expiration of such period the court decides that such patent has been in-

fringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, or

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of such court decision.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of forty-five days from the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of title 28, for a declaratory judgment with respect to the patent. Any action brought under section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(iv) If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing such a certification, the application shall be made effective not earlier than one hundred and eighty days after—

(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or

(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,

whichever is earlier.

(C) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(D)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on Sep-

tember 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b) of this section.

(ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years

o have elapsed from the date of approval of the sub-
ection (b) application.

(iii) If an application submitted under subsection
b) of this section for a drug, which includes an active
ngredient (including any ester or salt of the active
ngredient) that has been approved in another appli-
ation approved under subsection (b) of this section, is
pproved after September 24, 1984, and if such appli-
ation contains reports of new clinical investigations
other than bioavailability studies) essential to the ap-
proval of the application and conducted or sponsored
by the applicant, the Secretary may not make the ap-
proval of an application submitted under this subsec-
ion for the conditions of approval of such drug in the
ubsection (b) application effective before the expir-
ation of three years from the date of the approval of
he application under subsection (b) of this section for
uch drug.

(iv) If a supplement to an application approved
nder subsection (b) of this section is approved after
September 24, 1984, and the supplement contains re-
ports of new clinical investigations (other than bioa-
vailability studies) essential to the approval of the sup-
plement and conducted or sponsored by the person
ubmitting the supplement, the Secretary may not
nake the approval of an application submitted under
his subsection for a change approved in the supple-
nent effective before the expiration of three years
rom the date of the approval of the supplement under
ubsection (b) of this section.

(v) If an application (or supplement to an application) submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from September 24, 1984.

(6) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—

(A) for the same period as the withdrawal or suspension under subsection (e) of this section or this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary

determines that the withdrawal from sale is not for safety or effectiveness reasons.

(7)(A)(i) Within sixty days of September 24, 1984, the Secretary shall publish and make available to the public—

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) of this section before September 24, 1984;

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) of this section or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (b) or (c) of this section respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(B) A drug approved for safety and effectiveness under subsection (c) of this section or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or September 24, 1984, whichever is later.

(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under paragraph (6) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

(i) for the same period as the withdrawal or suspension under subsection (e) of this section or paragraph (6), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(8) For purposes of this subsection:

(A) The term "bioavailability" means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

(B) A drug shall be considered to be bioequivalent to a listed drug if—

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

(9) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of—

(A) the name of the applicant,

(B) the name of the drug covered by the application,

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment.

The information the Secretary is required to maintain under this paragraph with respect to an application submitted under this subsection shall be made available to the public after the approval of such application.

. 35 U.S.C. 271 (2006 & Supp. V 2011) provides in elevant part:

nfringement of patent

* * * * *

(e)(1) It shall not be an act of infringement to ıake, use, offer to sell, or sell within the United States r import into the United States a patented invention ɔther than a new animal drug or veterinary biological roduct (as those terms are used in the Federal Food,)rug, and Cosmetic Act and the Act of March 4, 1913) hich is primarily manufactured using recombinant)NA, recombinant RNA, hybridoma technology, or

other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit—

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent,

(B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151-158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent, or

(C)(i) with respect to a patent that is identified in the list of patents described in section 351(1)(3) of the Public Health Service Act (including as provided under section 351(1)(7) of such Act), an application seeking approval of a biological product, or

(ii) if the applicant for the application fails to provide the application and information required under section 351(1)(2)(A) of such Act, an application seeking approval of a biological product for a

patent that could be identified pursuant to section 351(1)(3)(A)(i) of such Act,

f the purpose of such submission is to obtain approval ınder such Act to engage in the commercial manufac-ıure, use, or sale of a drug, veterinary biological pro-luct or biological product claimed in a patent or the ıse of which is claimed in a patent before the expira-tion of such patent.

(3) In any action for patent infringement brought ınder this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2)—

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product,

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product.

(D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(1)(6) of such Act, and the biological product has not yet been approved because of section 351(k)(7) of such Act.

The remedies prescribed by subparagraphs (A), (B), C), and (D) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection

(b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

* * * * *

RESPONDENT'S BRIEF

FEB 21 20

No. 12-416

In the Supreme Court of the United States

FEDERAL TRADE COMMISSION,
Petitioner,

v.

ACTAVIS, INC., ET AL.,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF FOR RESPONDENT ACTAVIS, INC. (f/k/a WATSON PHARMACEUTICALS, INC.)

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QUESTION PRESENTED

Whether the federal antitrust laws permit the settlement of patent litigation between a patent-holding brand-name pharmaceutical manufacturer and a generic manufacturer when the terms of the settlement do not exceed the potential exclusionary scope of the patent.

RULE 29.6 STATEMENT

The Rule 29.6 statement contained in the brief filed at the certiorari stage is amended as follows.

On January 24, 2013, Respondent Watson Pharmaceuticals, Inc., officially changed its name to Actavis, Inc. Pursuant to Rule 29.6 of the Rules of this Court, Respondent Actavis, Inc. states the following:

Actavis, Inc. is a publicly held company that has no parent corporation, and no publicly held company owns 10% or more of its stock.

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INTRODUCTION

This case arises at the intersection of antitrust law, patent law, and the law of settlement. The Government's proposed approach does violence to all three. The Court of Appeals' approach, in contrast, respects the appropriate boundaries and principles of each body of law.

The central question is whether a settlement of *bona fide* patent litigation unlawfully restrains trade, where the patent was not procured by fraud and the settlement terms do not exceed the scope of the patent's exclusionary potential. Critical to this inquiry is the presence of the patent, which is presumed to be valid and grants its holder the *lawful* right to exclude competition within its scope. Despite the obvious importance of the patent to the antitrust analysis of the settlement agreements, the new test proposed by the Government lacks any reference to the patent's potential exclusionary effect. Indeed, the Government would have this Court write the patent out of the equation entirely.

Two fundamental errors in the Government's Question Presented highlight the Government's approach. Pet. Br. I. First, the Government characterizes a patentee as only "assertedly" holding a patent. However, a patentee to whom a patent has been granted by the U.S. Patent and Trademark Office (PTO) undisputedly holds that patent (not "assertedly"), with its attendant statutory right to exclude and presumption of validity. 35 U.S.C. §§ 154(a)(1), 282(a).

The Government's second error in its Question Presented is to disregard a critical element of the

Eleventh Circuit's approach—whether the scope of the patent's exclusionary potential has been exceeded by the settlement's terms. *See* Pet. Br. I ("[w]hether reverse-payment agreements are per se lawful unless the underlying patent litigation was a sham or the patent was obtained by fraud, or instead are presumptively anticompetitive and unlawful"). The Government's statement of the question is a serious misstatement of the Court of Appeals' holding: it omits the fundamental element that the settlement must not exceed the patent's exclusionary boundaries, and may be challenged under the antitrust laws if it does.

Nor is the Government's disregard of the patent limited to the Question Presented. The Government's brief barely mentions the complaint's numerous allegations that the patentee here was "unlikely to prevail" in its patent infringement suit. The brief also fails to mention that these very allegations formed the core of the Federal Trade Commission's (FTC) arguments to the court below, allegations that the Eleventh Circuit found to be key in concluding that the antitrust analysis does not require an assessment of which party was "more likely" to prevail. The Government's effort to distance itself from its own allegations at this stage is remarkable and telling. Because resting liability on a post-settlement evaluation of litigation probabilities would be extraordinary and fraught with problems, the Government now scorns that endeavor. But the logic of the Government's position, as well as its actual position *in this case*, requires precisely such an ill-advised inquiry.

The Government urges an ambiguous, burdensome, and improper rule. Its rule relies solely on the presence of a "payment" as the means of identifying supposedly anticompetitive patent litigation settlement agreements, and is premised upon the radical proposition that a patent is entitled to no weight at all unless and until it is proven valid and infringed in litigation. The rule, moreover, fails to qualify for "quick look" review as established by this Court, and improperly shifts the burden to defendants to disprove the elements of a plaintiff's *prima facie* case.

For the reasons set forth herein, this rule is logically incoherent, does not comport with this Court's precedent, and fails to provide an appropriate resolution of the principles of antitrust law, patent law, and the law of settlement.

In contrast to the Government's flawed presumption of illegality, the scope-of-the-patent approach applied by the Eleventh Circuit provides a clear and doctrinally sound mode of analysis for patent litigation settlements. Under this straightforward approach, "absent sham litigation or fraud in obtaining the patent," a so-called "reverse-payment" settlement does not violate the antitrust laws "so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." Pet. App. 28a.

The Court should reject the Government's misguided test and affirm the decision of the court below.

STATEMENT

1. To obtain approval for a new drug, a brand-name pharmaceutical manufacturer must submit a New Drug Application (NDA) to the Food and Drug

Administration (FDA) demonstrating the safety and efficacy of its product. 21 U.S.C. § 355(b).[1] Generic drug approval is governed by the "Hatch-Waxman Amendments" of 1984. *See* Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585. Hatch-Waxman's basic goal was to balance the need for pharmaceutical innovation with the need for generic drug competition. *See, e.g., Teva Pharm. Indus. Ltd.* v. *Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005). Accordingly, a generic manufacturer may submit an Abbreviated New Drug Application (ANDA) relying upon the safety and efficacy data in the brand-name manufacturer's NDA and demonstrating, among other things, that the proposed generic product is bioequivalent to the brand-name drug. 21 U.S.C. § 355(j)(2)(A)(iv).

An NDA applicant must provide the FDA with the patent number and expiration date of "any patent which claims the drug . . . or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1); *see also* 21 C.F.R. § 314.53 (2000). If the NDA is approved, the FDA will list the patent in its "Orange Book," *see* 21 C.F.R. § 314.53, and an ANDA must contain a certification regarding that patent. 21 U.S.C. § 355(j)(2)(A)(vii).

Relevant here is the "Paragraph IV" certification, a statement alleging that the listed patent is invalid or unenforceable, that the generic version would not

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[1] Unless otherwise noted, citations to Title 21 of the United States Code refer to the 2000 edition. *See* Pet. Br. 2 n.1.

infringe the patent, or both. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Filing a Paragraph IV certification is deemed a constructive act of infringement; the brand-name drug company may immediately sue the ANDA filer for patent infringement. 35 U.S.C. § 271(e)(2)(A).

When a lawsuit is filed within 45 days of receipt of notice of the Paragraph IV ANDA filing, the FDA generally may not grant final approval to the ANDA for 30 months after the lawsuit is filed or until the ANDA filer prevails in litigation, whichever occurs sooner. 21 U.S.C. § 355(j)(5)(B)(iii). If the brand-name drug company prevails, the district court must issue an order preventing FDA approval of the generic alternative from becoming final before the patent expires. *Id.* § 355(j)(5)(B)(iii)(II); 35 U.S.C. § 271(e)(4)(A).

Under Hatch-Waxman, the first ANDA filer for a generic version of the brand-name drug product is under certain circumstances entitled to 180 days of marketing exclusivity for its generic product, during which time the FDA will not grant final approval to subsequently-filed ANDAs. *See* 21 U.S.C. § 355(j)(5)(B)(iv).[2]

2. The agreements at issue relate to AndroGel, a brand-name prescription testosterone replacement drug used to treat hypogonadism. Second Amended

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[2] 21 U.S.C. § 355 was amended in part by Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, 2448 (MMA). The MMA generally does not apply to pre-MMA ANDAs, including those at issue here. *Id.* §§ 1101(c), 1102(b), 117 Stat. at 2456, 2460 (effective date provisions).

Complaint (Complaint) ¶¶ 1, 31-33, J.A. 28, 36-37; Pet. App. 38a. Unimed Pharmaceuticals, Inc. (Unimed) filed an NDA for AndroGel that was approved by the FDA in February 2000. Complaint ¶ 33, J.A. 37; Pet. App. 39a.[3]

Unimed and its development partner, Besins Healthcare S.A. (Besins), applied for a patent on the AndroGel formulation and methods of using that formulation in August 2000; the PTO granted the application and issued U.S. Patent No. 6,503,894 ('894 patent) in January 2003. Complaint ¶¶ 39, 42, J.A. 38, 39. The '894 patent expires in August 2020. Complaint ¶ 43, J.A. 39.

In May 2003, Respondent Actavis, Inc., formerly known as Watson Pharmaceuticals, Inc. (Watson), submitted a Paragraph IV ANDA, seeking FDA approval to market a bioequivalent, generic version of AndroGel. Complaint ¶ 44, J.A. 39. As the first ANDA filer, Watson was eligible for the 180-day marketing exclusivity. Complaint ¶45, J.A. 40. Respondent Paddock Laboratories, Inc. (Paddock), filed its own Paragraph IV ANDA shortly thereafter. Complaint ¶¶ 44, 45, J.A. 39-40.

Unimed and Besins filed patent infringement suits against Watson and Paddock in August 2003 in the United States District Court for the Northern District of Georgia. Complaint ¶ 47, J.A. 40; Pet. App. 41a-42a. Watson and Paddock denied infringement and alleged that the '894 Patent was invalid and/or unenforceable. Complaint ¶¶ 3, 88-89, J.A. 28,

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[3] Respondent Solvay Pharmaceuticals, Inc. (Solvay) later acquired Unimed. Solvay is now known as AbbVie Products LLC.

54-55.[4] From late 2003 to the middle of 2005, the parties engaged in discovery, scheduling, and other initial litigation matters. Pet. App. 42a. By late 2005, the parties had filed claim construction briefs, and Watson and Par/Paddock had filed motions for partial summary judgment, Complaint ¶ 90, J.A. 55; Pet. App. 42a-43a; these partial summary judgment motions would not have been case-dispositive even if Watson and Par/Paddock had prevailed. Br. for Appellees Unimed et al., at 10, *FTC* v. *Watson*, No. 10-12729-DD (11th Cir. filed Nov. 10, 2010).

In January 2006, the 30-month stay expired and Watson received final FDA approval for its ANDA; at that point, Watson legally could have launched its generic drug despite the pending infringement suit. Complaint ¶¶ 47, 52, J.A. 40, 41. Such a launch is referred to as an "at-risk launch." Had Watson launched but ultimately lost the infringement action, it would have been liable for significant damages. Watson did not launch its generic drug "at risk" in January 2006 or at any time thereafter. Complaint ¶ 65, J.A. 46.

In September 2006, the parties settled both patent infringement cases prior to any decision on claim construction or on the pending partial summary judgment motions. Complaint ¶¶ 65, 68, 76, 80, J.A. 46, 47, 49, 50; Pet. App. 12a, 43a. The terms of both settlements reflected an agreement to dismiss the patent cases, as well as the grant of licenses to Watson and Par/Paddock to launch their respective generic

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[4] Respondent Paddock partnered with Par Pharmaceutical Companies, Inc. (Par), another generic drug company, to share litigation costs. Complaint ¶¶ 2, 46, J.A. 28, 40.

1% testosterone gels in August 2015—five years *before* expiration of Unimed's '894 patent. Complaint ¶¶ 65, 76, J.A. 46, 49; Pet. App. 43a-44a. As part of its settlement, Watson relinquished its claim to the 180-day marketing exclusivity. *See* Pet. App. 49a.

In business deals concluded at the same time as the settlement agreements, Watson agreed that its sales force would promote AndroGel to urologists. Complaint ¶ 66, J.A. 46. In return, Solvay agreed to pay Watson based on the sale of AndroGel to urologists. Complaint ¶¶ 64, 66, J.A. 45. Solvay allegedly anticipated that Watson would receive approximately $20-30 million annually. Complaint ¶ 66, J.A. 45. As for Par/Paddock, Par agreed that its sales force would promote AndroGel to primary care physicians from 2006 until 2012, and Solvay agreed to pay Par $10 million annually for these services. Complaint ¶ 77, J.A. 49. Paddock would provide backup manufacturing capacity for AndroGel from 2006 until 2012, and Solvay agreed to pay Paddock $2 million annually for this capacity. *Ibid.*

3. Shortly after the settlements, the FTC initiated an investigation into whether Solvay, Watson, and Par/Paddock had violated antitrust law by entering into the settlement agreements and business arrangements. *See* Pet. App. 45a. The FTC's investigation continued for over two years.

4. On January 27, 2009, the FTC filed suit in the United States District Court for the Central District of California, challenging the two patent settlements under the antitrust laws. On respondents' motion, the cases were transferred to the Northern District of Georgia. *FTC* v. *Watson Pharm., Inc.*, 611 F. Supp. 2d 1081 (C.D. Cal. 2009). Once in Georgia, this case

and parallel private lawsuits were assigned to the same judge who had presided over the underlying patent lawsuits.

The Complaint emphasized the FTC's views about the likely outcome of the patent litigation as an important element of its antitrust case. The Complaint included an entire section alleging that "Solvay's Patent Was Unlikely to Prevent Generic Competition to AndroGel," J.A. 53, comprising seven paragraphs of allegations purporting to support the conclusion that "Solvay was not likely to prevail in each of its patent lawsuits to prevent competition to AndroGel." Complaint ¶ 86, J.A. 53. The Complaint alleged that the settlements violated section 5(a) of the FTC Act, 15 U.S.C. § 45(a)(1), and sought declaratory and injunctive relief. Complaint, Prayer for Relief, J.A. 62.

Respondents moved to dismiss. On February 22, 2010, the district court dismissed the Complaint, relying on Eleventh Circuit precedent. Pet. App. 47a-52a. The court recognized that, in evaluating an antitrust challenge to a Hatch-Waxman patent settlement, Eleventh Circuit precedent required consideration of "(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects." *Id.* 48a (internal quotation marks omitted). The court found that the settlements did not exceed the scope of the patent's exclusionary potential given the lack of any allegation by the FTC that the agreements "exclude[d] any product other than generic AndroGel," and the undisputed fact that the settlements in fact "provide[d] for five years less exclusion than the '894 patent." *Id.* 48a-49a. Because the FTC had "not allege[d] that the

settlements exceed the scope of the '894 patent," the district court ruled that "it [did] not matter if the Defendants settled their patent disputes with reverse payments." *Id.* 52a.[5]

5. The Court of Appeals affirmed. Pet. App. 1a-36a. Rejecting the FTC's arguments that Eleventh Circuit precedent should be read to consider the strength of the patent, and in the alternative that reverse-payment settlements should be presumptively unlawful restraints of trade, the court hewed to its prior rule. Accordingly, "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." *Id.* 28a.[6]

The Court of Appeals rejected the FTC's argument that it should find a "reverse-payment" settlement unlawful "if, viewing the situation objectively as of the time of settlement, it is more likely than not that the patent would not have blocked generic entry ear-

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[5] The district court permitted private treble-damage suits challenging the same settlement agreements to proceed because those plaintiffs—unlike the FTC—alleged that the underlying patent litigation was sham litigation. Pet. App. 57a. Summary judgment was granted in defendants' favor on the sham litigation claims. *In re Androgel Antitrust Litig. (No. II)*, No. 1:09-MD-2084-TWT, 2012 WL 5352986 (N.D. Ga. Oct. 30, 2012). Appeals from that decision have been stayed pending the Court's resolution of this case. *See, e.g., Meijer Inc.* v. *Unimed Pharm. Inc., et al.*, No. 12-15562-B (11th Cir. docketed Oct. 30, 2012).

[6] The court defined a so-called "reverse-payment" settlement as one where "a patent holder pays the allegedly infringing generic drug company to delay entering the market until a specified date[.]" Pet. App. 3a.

lier than the agreed-upon entry date." *Id.* 29a (internal quotation marks omitted). Emphasizing that its decisions "focus on the potential exclusionary effect of the patent, not the likely exclusionary effect," the court characterized the FTC's suggested approach as requiring an "after-the-fact calculation of how 'likely' a patent holder was to succeed in a settled lawsuit if it had not been settled." *Id.* 30a, 32a. Such a "retroactive[] predicti[on] from a past perspective [of] a future that never occurred" was "too perilous an enterprise to serve as a basis for antitrust liability and treble damages," and would "impose heavy burdens on the parties and the courts." *Id.* 32a, 33a. Concerned that our legal system "can ill afford" an approach that would require mining through "mountains of evidence" to assay the infringement claim, thereby "undo[ing] much of the benefit of settling patent litigation" and "discourag[ing] settlements," the court declined the FTC's invitation to "attempt to decide how some other court in some other case at some other time was likely to have resolved some other claim if it had been pursued to judgment." *Id.* 33a, 36a. The Court of Appeals denied rehearing en banc. *Id.* 62a-63a.

SUMMARY OF ARGUMENT

This case arises at the intersection of patent law, antitrust law, and the law of settlement. It presents the question of how to adjudge, under the antitrust laws, the legality of final settlements of patent litigation, where the patent was not procured by fraud, the litigation was not a sham, and the settlement does not exceed the patent's exclusionary potential.

I. The Government's proposed solution is to apply a "quick look." The Government would declare pre-

sumptively illegal under the antitrust laws any settlement of patent litigation between a brand-name drug manufacturer and a generic drug applicant that provides for licensed generic entry at some future date, if a "payment" is made to the generic applicant—even when the entry date would be before the patent's expiration. Pet. Br. 2, 17. The Government bases its presumption upon what the Government calls a "natural inference" that the "payment has purchased an additional increment of market exclusivity." *Id.* 36.

Under the Government's test, if an antitrust plaintiff alleges and establishes that (i) a settlement agreement provides for non-immediate generic entry, and (ii) the generic patent infringement defendant received a "payment," the settlement is presumptively unlawful and the burden shifts to the settling parties to prove that the "payment" was for something other than a "delay" in generic entry. *Id.* 37-38. This Court's precedent, however, does not permit the "quick look" review—and presumptive illegality—the Government seeks. *See Cal. Dental Ass'n* v. *FTC*, 526 U.S. 756, 778 (1999).

A. The patent laws provide a patentee (here, the brand-name drug manufacturer) with a *lawful* right to exclude alleged infringers. 35 U.S.C. § 154(a)(1); *Dawson Chem. Co.* v. *Rohm & Haas Co.*, 448 U.S. 176, 215 (1980). This Court's antitrust precedent recognizes that, so long as the patentee operates within the exclusionary bounds of its patent monopoly, the antitrust laws do not forbid the patentee's conduct. *United States* v. *Gen. Elec. Co.*, 272 U.S. 476, 485, 489 (1926); *United States* v. *Line Material Co.*, 333 U.S. 287, 300 (1948). The Government's

suggested approach simply disregards the patent's exclusionary potential. *See infra* pp. 16-20.

B. Moreover, this Court has held that "quick look" review is available only where the "great likelihood of anticompetitive effects can easily be ascertained." *Cal. Dental*, 526 U.S. at 770. The Government has failed to show "obvious" and "actual[] anticompetitive effects" flowing from the targeted settlements sufficient to justify a presumption that the challenged agreements are always, or almost always, illegal. *Id.* at 771, 775 n.12. Leading economists—and until recently, the Department of Justice (DOJ)—agree that the mere presence of a "payment" to the generic applicant is, without more, an insufficient indicator of the competitive effects of a patent litigation settlement. Nor do empirical data support the truncated analysis. The Government has failed to allege actual or theoretical anticompetitive effects that would justify quick look review. *See infra* pp. 20-31.

C. Apart from the lack of justification for "quick look" review, the Government's test reveals flaws fatal to its practical application. As proposed, the antitrust plaintiff's *prima facie* case would consist of showing (i) a "payment" to the generic applicant and (ii) a non-immediate generic entry date. Pet. Br. 2, 37. The first element, the Government's conception of "payment" in this context, is hopelessly ambiguous. Though the Government now asserts that this Court's consideration of the "payment" question need not stray beyond the facts presented (*i.e.*, alleged direct cash payments constituting overpayment for services rendered), the FTC previously argued in this case that "payment" encompasses provision of eco-

nomic value to the generic applicant *in any form*. The second element of the *prima facie* case, deferred entry, would be adequately pled by a simple allegation that the settlement contemplated a non-immediate date for licensed generic entry, regardless of whether that date represented a delay beyond what might have been agreed but for the payment. Because the antitrust plaintiff need not show that the "payment" actually occasioned any delay, the proposed *prima facie* test is unmoored from the relevant antitrust inquiry and sets an alarmingly low bar for pleading an antitrust violation. *See infra* pp. 31-36.

D. Not only is the *prima facie* case flawed, but the Government's envisioned rebuttal would preclude defendants from presenting procompetitive justifications based on patent merits, rendering the rule a *per se* prohibition. The purported anticompetitive effect of a "reverse-payment" settlement hinges upon allegedly delayed generic entry. Yet whether the agreed-upon generic entry date represented an *actual* delay compared to the likely date of generic entry, had the litigation been litigated to conclusion, can be ascertained only from a relitigation of the patent merits. After all, had the patent been upheld as valid and infringed, the provision for generic entry prior to patent expiration would be clearly procompetitive. Precluding defendants from responding to the presumption of illegality by addressing the patent merits—as the Government now proposes—would be unjust and inconsistent with this Court's precedent. At the same time, as the Court of Appeals emphasized (and as the Government apparently now recognizes), premising liability on a speculative determination about possible litigation outcomes would

be conceptually flawed and inherently unreliable. *See infra* pp. 36-39.

E. The Government's approach also would have consequences that the FTC surely cannot intend. The uncertainty generated by its ambiguous and burdensome rule would have a chilling effect on generic patent challenges and upon pharmaceutical innovation, and would impose unwarranted burdens upon the judicial system. *See infra* pp. 39-46.

II. The correct mode of antitrust analysis is the scope-of-the-patent test applied by the Court of Appeals, in which "absent sham litigation or fraud in obtaining the patent," a so-called reverse-payment settlement does not violate the antitrust laws "so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." Pet. App. 28a. This approach is mandated by antitrust law, patent law, and the law of settlement. This approach appropriately subjects settlements to antitrust scrutiny if the settlements (i) exceed the bounds of the patent monopoly, *United States* v. *Singer Mfg. Co.*, 374 U.S. 174, 196-97 (1963); (ii) settle sham litigation, *Professional Real Estate Investors, Inc.* v. *Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61 (1993) (*PRE*); or (iii) involve a patent obtained through fraud on the PTO. *Walker Process Equip., Inc.*, v. *Food Mach. & Chem. Corp.*, 382 U.S. 172, 177 (1965). Under this approach the Complaint failed to state a claim and was properly dismissed. *See infra* pp. 46-57.

ARGUMENT

I. The Government's Proposed Test is Erroneous.

Unhappy with the approach taken by the court below—which reflects the near-unanimous view of the courts of appeals to have considered the issue—the Government urges this Court to classify as presumptively unlawful all settlements of Hatch-Waxman patent litigation that include what it deems a "payment" from the patent holder to the generic manufacturer and non-immediate entry by the generic manufacturer. The Government's position is inconsistent with well-settled principles of antitrust law, patent law, and the law of settlement.

The Government's suggested approach appears to be as follows: "Reverse-payment agreements should . . . be treated as presumptively anticompetitive under a 'quick look' rule of reason analysis." Pet. Br. 17. First, a plaintiff must establish the existence of a reverse-payment agreement. *Id.* 37. The Government defines such an agreement as one whereby "a patentee (the brand-name manufacturer) agrees to pay an accused infringer (its would-be generic competitor), and the competitor agrees that it will not enter the market for a specified period of time." *Id.* 2. Second, once the plaintiff has made out this *prima facie* case, the settlement agreement is presumed illegal and the burden shifts to the antitrust defendants to rebut the presumption. *Id.* 37. The defendants can rebut the presumption by showing that (1) "'any money that changed hands was for something other than delay, . . . such as the generic manufacturer's provision of property or services unrelated to the brand-name manufacturer's

monopoly,'" *ibid.* (quoting *In re K-Dur Antitrust Litigation*, 686 F.3d 197, 218 (3d Cir. 2012)); (2) the payment was commensurate with litigation costs that the brand-name manufacturer avoided by settling, *id.* 38; or (3) in "likely rare" circumstances, the existence of "certain unusual business or litigation justifications" justified the payment. *Ibid.*[7]

The Court should decline the Government's invitation. The proposed test is not only internally incoherent, but it also is inconsistent with patent rights, lacks a sound basis in this Court's antitrust precedent, and reflects an improper effort to shift the burden of persuasion to defendants to justify a settlement of litigation. Contrary to the Government's assertions, adoption of this test would lead to consumer harm in the form of fewer generic patent challenges and reduced innovation. It would burden the judicial system by forcing parties to litigate their patent disputes to conclusion when they would prefer to settle. Those that did settle with a future entry date and an alleged value transfer to the generic manufacturer would face the potent threat of collateral attack by treble-damage-seeking antitrust plaintiffs benefiting from an easy-to-establish *prima facie* case and a presumption that the settlement was illegal. Although the Government now claims patent merits are irrelevant to the defense, once embroiled in the antitrust case, the settling parties would have

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[7] The Third Circuit stated the test as follows: "the finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some procompetitive benefit." *K-Dur*, 686 F.3d at 218.

to be afforded the opportunity to disprove the presumption of delayed generic entry. The only way to disprove delay, however, is through the "turducken" task of relitigating the patent case inside the antitrust case, Pet. App. 36a, defeating the repose obtained through settlement.

A. The Government's Test Disregards the Patent.

The Constitution endows Congress with the power "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8. Congress, in turn, has granted a patentee the right to exclude others from profiting from his patented invention. 35 U.S.C. § 154(a)(1) (providing "a grant to the patentee . . . of the right to exclude others from making, using, offering for sale, or selling the invention . . . ."); *Dawson*, 448 U.S. at 215. The Patent Act also provides that a patent is "presumed valid." 35 U.S.C. § 282(a).

Under this Court's longstanding precedents, the scope of the patent forms the zone within which the patent holder may operate without facing the specter of antitrust liability. *See Line Material*, 333 U.S. at 300 ("[T]he precise terms of the grant define the limits of a patentee's monopoly and the area in which the patentee is freed from competition of price, service, quality or otherwise"); *Gen. Elec. Co.*, 272 U.S. at 485, 489 ("[I]t is only when . . . [the patentee] steps out of the scope of his patent rights" that he comes within the operation of the Sherman Act); *Simpson* v. *Union Oil Co. of Cal.*, 377 U.S. 13, 24 (1964) (the patent laws "are *in pari materia* with the antitrust laws

and modify them *pro tanto*"). This Court has long recognized that settlement of patent litigation does not, without more, violate the antitrust laws. *Standard Oil Co. (Ind.)* v. *United States*, 283 U.S. 163, 171 (1931) ("Where there are legitimately conflicting claims or threatened interferences, a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act.").

The Government nevertheless urges the Court to adopt an antitrust analysis for patent litigation settlements that disregards the patent. The effect is to treat the patent as though it were presumptively *in*valid—indeed, the Government explicitly takes the position that the patent has *no* scope until courts have established its validity and coverage in litigation. Pet. Br. 25-26 ("simply holding a patent does not result in the automatic exclusion of potential rivals;" "[t]o enforce a contested patent, a patentee must prove that the accused product or process falls within the scope of the patent's claims as properly construed."); *id.* 40 (parties unable to settle without a payment need to litigate to final judgments that "reflect determinations by judges and juries, based on adversary presentations by the brand-name and generic manufacturers, as to the *actual* exclusionary force of the relevant patents.") (emphasis in original).

That the Government now endorses a test devoid of reference to the patent's exclusionary potential is all the more remarkable given the Complaint's allegations. In contrast to the Government's position here, where it asserts that consideration of the patent merits is unnecessary, the Complaint contains a section titled "Solvay's Patent was Unlikely to Prevent Generic Competition to AndroGel," comprised of

seven paragraphs of allegations purporting to establish that the patentee "was not likely to prevail" in the patent litigation. Complaint ¶¶ 86-92, J.A. 53-55. Indeed, those allegations formed the core of the FTC's opening arguments to the Eleventh Circuit, *see* Br. for Appellant FTC 20-37, *FTC* v. *Watson Pharmaceuticals, Inc.*, No. 10-12729-DD (11th Cir. filed July 26, 2010), and were the "lynchpin" allegations that the Eleventh Circuit rejected. Pet. App. 14a, 30a.[8]

Recognition of the patent's lawful exclusionary potential is crucial to the correct antitrust analysis. *Verizon Commc'ns, Inc.* v. *Law Offices of Curtis V. Trinko*, 540 U.S. 398, 411 (2004); *E. Bement & Sons* v. *Nat'l Harrow Co.*, 186 U.S. 70, 88 (1902) (the "most material fact" to antitrust analysis of patent-related agreements "is that the agreements concern articles protected by letters patent"). The Government's conspicuous disregard of the patent—save for where patent validity and scope are established in bitter-end litigation—is itself a reason to reject the Government's test.

B. "Quick Look" Review is Not Warranted.

Categorical condemnation of certain types of agreements is typically reserved only for those restraints classified as *per se* unlawful. *Leegin Creative Leather Prods., Inc.* v. *PSKS, Inc.*, 551 U.S. 877, 886 (2007) (the *per se* rule "treat[s] categories of re-

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[8] The "not likely to prevail" allegations were contained in the original Complaint (Dkt. No. 4, J.A. 8) and First Amended Complaint (FAC) (Dkt. No. 8, J.A. 8), both filed in California prior to transfer. *E.g.*, FAC at 21, ¶ 92. Thus, the Government cannot argue that the allegations were merely an effort to comply with what it believed to be Eleventh Circuit precedent.

straints as necessarily illegal" and "eliminates the need to study the reasonableness of an individual restraint in light of the real market forces at work"). *Per se* treatment "is appropriate only after courts have had considerable experience with the restraint at issue" and "only if courts can predict with confidence that it would be invalidated in all or almost all instances under the rule of reason." *Id.* at 886-87. Where "the economic impact of certain practices is not immediately obvious," *per se* rules are inappropriate. *Id.* at 887 (internal quotation marks omitted).

Here the Government advocates for application of a truncated, "quick look" approach. Pet. Br. 17, 33-40. "Quick look" review applies "where the restraint is sufficiently threatening to place it presumptively in the *per se* class, but lack of judicial experience with a significant element requires at least some consideration of proffered defenses or justifications." 11 Philip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶1911a (3d ed. 2011). Only when "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets" may this shortcut apply. *Cal. Dental*, 526 U.S. at 770. Such truncated review is reserved for "business activities that are so plainly anticompetitive that courts need undertake only a cursory examination before imposing antitrust liability," *Texaco, Inc.* v. *Dagher*, 547 U.S. 1, 7 n.3 (2006); "quick-look analysis carries the day when the great likelihood of anticompetitive effects can easily be ascertained." *Cal. Dental*, 526 U.S. at 770.

The burden of showing that the challenged agreement has a substantial anticompetitive effect

ordinarily rests with the antitrust plaintiff. *United States* v. *Arnold, Schwinn & Co.*, 388 U.S. 365, 374 n.5 (1967) ("The burden of proof in antitrust cases remains with the plaintiff, deriving such help as may be available in the circumstances from particularized rules articulated by law—such as the per se doctrine."), *overruled on other grounds by Cont'l T.V., Inc.* v. *GTE Sylvania, Inc.*, 433 U.S. 36, 58-59 (1977); *Times-Picayune Publ'g Co.* v. *United States*, 345 U.S. 594, 622 (1953) ("Under the broad general policy directed by §1 against unreasonable trade restraints, guilt cannot rest on speculation;" holding that the government had failed to meet its burden of showing "actual unlawful effects [or] facts which radiate a potential for future harm.").

In determining whether an alleged restraint qualifies for "quick-look" review, the court must first "properly identif[y] the theoretical basis for the anticompetitive effects [of the restraint] and consider[] whether the effects actually are anticompetitive" before the burden may be shifted to an antitrust defendant to show "empirical evidence of procompetitive effects." *Cal. Dental*, 526 U.S. at 775 n.12. However, where "the circumstances of the restriction are somewhat complex, *assumption alone will not do*." *Ibid.* (emphasis added). Rather, the inquiry into allegedly anticompetitive effects must be sufficiently rigorous to justify shifting the burden. *Id.* at 776 (criticizing the "leniency of [the Court of Appeals'] enquiry into evidence of the restrictions' anticompetitive effects" and the court's "adversion to empirical evidence at the moment of this implicit burden shifting" to the defendants); *see also Major League Baseball Props., Inc.* v. *Salvino, Inc.*, 542 F.3d 290, 340 n.10 (2d Cir. 2008) (Sotomayor, J., concurring)

("When empirical analysis is required to determine a challenged restraint's net competitive effect, neither a *per se* nor a quick-look approach is appropriate . . . . ").

The "ultimate focus" of the inquiry is to form a judgment about the restraint's "impact on competition." *NCAA* v. *Bd. of Regents of the Univ. of Okla.*, 468 U.S. 85, 103-04 (1984).

1. Here, the Government has fallen short of showing that reverse-payment settlements have "obvious" and "actual[] anticompetitive effects" sufficient to justify a quick look approach and a presumption of illegality. *Cal. Dental*, 526 U.S. at 771 & 775 n.12. Disregarding the patent's potential exclusionary scope, the Government relies on unwarranted assumptions and equivocal data to support its sweeping conclusion that "the presence of a reverse payment raises concern about the integrity of the competition restricting features of the settlement." Pet. Br. 29. In fact, the literature explains that "reverse-payment" agreements often have pro-competitive virtues, which DOJ itself until recently had acknowledged.

a. As a threshold matter, the Government cannot demonstrate *actual* anticompetitive effects, and instead substitutes a proxy that merely *assumes* them. The assumption is that, if Paragraph IV patent litigants were prohibited from settling with a payment, they would reach a settlement with a "deferred entry date" that "roughly corresponds to the parties' assessments of their likelihood of success in the litigation." *Id.* 28. If the parties are permitted to bargain with a payment, however, the Government assumes that the payment serves to delay entry "re-

gardless of the parties' assessments of the suit's likely outcome." *Id.* 29.

The Government's assumption that a "reverse payment" implies that the patent litigants could have reached a "better" settlement without a payment and with an earlier entry date is unwarranted and unproven. As noted economists have explained,

> there are many different sets of circumstances where the two firms will be unable to reach a mutually agreeable settlement without the payment of net consideration by the incumbent to the entrant. In the absence of such a payment, the firms will continue to litigate and the outcome of the litigation may be worse for consumers than the settlement that could have been achieved with a payment of net consideration because such settlements may result in entry sooner than the expected entry date under litigation. Th[e] invalid simple argument [that a settlement with an earlier entry date is available] *merely assumes* that an earlier entry date can substitute for the payment of net consideration. But . . . this assumption is inapplicable under at least the circumstances of asymmetric information, asymmetric expectations, and predictable entry by a nonlitigant before the end of the patent's life.

Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, 49 Antitrust Bull. 655, 676 (2004) (emphasis added); *id.* at 659.

Other economists and commentators agree that the mere presence of a payment is a poor indicator of the competitive effects of a particular settlement, and that settlements whose terms include a payment to the generic manufacturer can benefit consumers. *See, e.g.*, Bret Dickey, Jonathan Orszag & Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 Annals Health L. 367, 391 (2010) ("Under certain conditions, without the bargaining tool of a payment from the brand-name manufacturer to the generic manufacturer, the parties will be unable to reach agreement on a settlement, even if that settlement would benefit consumers."); Mark G. Schildkraut, *Patent-Splitting Settlements & the Reverse Payment Fallacy*, 71 Antitrust L.J. 1033, 1034 (2004) ("[A] reverse payment is necessary [in many circumstances] to resolve a patent litigation and that resolution is better for consumers than continued litigation"); Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles*, 15 Fed. Cir. B.J. 617, 618-619, 628-31 (2005) ("[T]here are a number of reasons why a settlement based on . . . a [simple] split [of the remaining patent term] may not be available," including "asymmetric time horizons and asymmetric risk profiles or expectations").[9]

This notion that reverse-payments have the procompetitive potential of achieving settlement, and

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[9] These commentators are all critical of an overly-restrictive rule limiting settlement options. While they are not all in agreement on the appropriate rule, as set forth in Section II, *infra*, the scope-of-the-patent approach is consistent with this Court's precedents.

even permitting early generic entry where it might otherwise not have occurred, has been recognized by courts of appeals that have adopted the scope-of-the-patent approach. *See, e.g.*, *Schering-Plough Corp.* v. *FTC*, 402 F.3d 1056, 1073 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 215 (2d Cir. 2006), *cert. denied*, 551 U.S. 1144 (2007); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1333 (Fed. Cir. 2008), *cert. denied*, 129 S. Ct. 2828 (2009).

Indeed, DOJ until recently was of the view that reverse-payment settlements have pro-competitive potential, and it explicitly disagreed with a presumption of illegality. In response to this Court's invitation, DOJ submitted a brief opposing certiorari in *Schering-Plough*. DOJ argued that "the public policy favoring settlements, and the statutory rights of patentees to exclude competition within the scope of their patents, would potentially be frustrated by a rule of law that subjected patent settlements involving reverse payments to automatic or near-automatic invalidation," and that "the Hatch-Waxman context creates a litigation dynamic that makes some settlements reasonable." Brief for United States as Amicus Curiae, *FTC* v. *Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273), 2006 WL 1358441, *10-11 (*Schering* U.S. Br.). Noting the "high degree of suspicion" of reverse-payments reflected in the FTC's approach, *id.* at *12, DOJ's view was that "the mere presence of a reverse payment in the Hatch-Waxman context is not sufficient to establish that the settlement is unlawful." *Id.* at *11. Although the Government now acknowledges its sudden volte-face, Pet. Br. 41 n.9, no explanation for it is provided. In light of this unexplained reversal, DOJ's newfound

enthusiasm for a presumption of illegality should be viewed with skepticism.

Economic analysis and judicial experience make clear that the purported "natural inference" that a reverse payment "has purchased an additional increment of market exclusivity," Pet. Br. 36, is an unsupported assumption. Accordingly, "the plausibility of competing claims about the effects of the [alleged restraints] rules out the indulgently abbreviated review" that the Government seeks; "[t]he obvious anticompetitive effect that triggers abbreviated analysis has not been shown." *Cal. Dental*, 526 U.S. at 778.

b. Not only does the Government's position rely on unwarranted assumptions, but empirical analyses cited in support of its position, *see* Pet. Br. 6-7, 44-45, either are flawed or fail to support the Government's far-reaching rule.

One statistic cited by the Government derives from a 2002 FTC report stating that "generic competitors prevailed over brand-name manufacturers with respect to 73% of the drug products that were the subject of a court decision in paragraph IV litigation initiated between 1992 and 2000." Pet. Br. 6, 44 (citing FTC, *Generic Drug Entry Prior to Patent Expiration* 10, 19-20 (July 2002), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf (2002 FTC Report)). This decade-old statistic is flawed. First, it fails to include many victories by patentees. *See* Protecting Consumer Access to Generic Drugs Act of 2007: Hearing Before the Subcomm. on Commerce, Trade, & Consumer Protection of the H. Comm. on Energy and Commerce, 110th Cong. 102-104 (2007) (prepared statement of Phillip A. Proger) (FTC baseline

for litigated cases excluded cases in which the same drug patent was litigated more than once). Second, to the extent it is offered as evidence of the general vulnerability of patents, the study's findings regarding trials adjudicating patent *validity* show that patentees prevailed 72% of the time. 2002 FTC Report at 20 (28% invalidity rate for patents where parties chose to litigate to conclusion). Third, the percentage of generic wins in the 2002 FTC Report is based on a universe of only 40 court decisions. *Id.* at 19-20. A more recent study on paragraph IV patent challenges considered 171 cases and found a far lower generic success rate. Adam Greene & D. Dewey Steadman, *Pharmaceuticals: Analyzing Litigation Success Rates*, RBC Capital Markets Corp., 4 (Jan. 15, 2010), http://amlawdaily.typepad.com/pharmareport.pdf (generics won 82 court rulings and lost 89).

Beyond the Paragraph IV context, another study is cited by the Government for the proposition that nearly half of *all* litigated patents are declared invalid. Pet. Br. 4 (citing statistic that 46% of all litigated patents were declared invalid). However, the same study notes that *pharmaceutical* patents were upheld 72.7% of the time. *See* John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 217 (1998).

Yet another study cited as illustrating the purported anticompetitive effects of reverse-payment settlements is a 2010 FTC report concluding that "settlements with reverse payments were associated with generic entry an average of nearly 17 months later than settlements without," and that "[s]uch agreements are demonstrably associated with delayed entry of generic competition, costing consumers

billions of dollars each year." Pet. Br. 31, 45 (citing FTC, *Pay for Delay: How Drug Company Pay-Offs Cost Consumers Billions*, 2 (2010), http://www.ftc.gov/os/2010/01/100112payfordelayrtp.pdf (2010 FTC Report)). Economists have criticized the FTC's analysis as "unreliable" and "oversimplified" in a way "that has material bearing on its utility and reliability for predicting generic entry or estimating costs under alternative rules." Bret Dickey, Jonathan Orszag & Robert Willig, *A Preliminary Economic Analysis of the Budgetary Effects of Proposed Restrictions on "Reverse Payment" Settlements*, 3 (August 10, 2010), http://www.compasslexecon.com/highlights/Documents/Dickey%20Orszag%20Willig%20CBO.pdf. These authors observe that, "[a]s a matter of economics, there is no sound rationale for assuming that the inclusion of a payment from the branded to the generic manufacturer as part of the settlement agreement *caused* the observed differences in entry dates by the generic manufacturers." *Id.* They conclude that the Congressional Budget Office estimate of billions of dollars in savings from increased restrictions on reverse-payment settlements is likely overstated because it is premised upon the FTC's flawed studies. *Id.* at 6-7.

Given the broad variation in the statistics and criticism of the methodology used in these studies, the cited studies fail to provide an empirical basis for judicial adoption of quick look review. *See Cal. Dental*, 526 U.S. at 775 n.12 (requiring "proper[] identif[ication] of the theoretical basis of the anticompetitive effects and consider[ation] [of] whether the effects actually are anticompetitive" before burden may be shifted to defendants).

c. Still another infirmity in the Government's proposed quick-look analysis is the false dichotomy between "reverse-payment" settlements and "entry-date-only" settlements. The Government argues that "reverse-payment" settlements ought to be subject to "quick-look" review because they supposedly "closely resemble" horizontal market allocation agreements that have been found to be *per se* illegal. Pet. Br. 15, 19, 33-35.[10] Yet while the Government acknowledges that entry-date-only settlements also are agreements among potential horizontal competitors that restrict competition, *id.* 25 (entry-date-only settlements equally "entail[] a restriction of competition"), these, in the Government's view, do not raise antitrust concerns at all because they lack a "payment." *Ibid.* ("antitrust liability [should not] ordinarily attach to a settlement by which the parties to paragraph IV litigation simply agree on a compromise date of generic entry."). The better analysis is to recognize that it is the *patent*, and not the payment, that is the source of the exclusion. That is why *Palmer* v. *BRG of Georgia, Inc.*, 498 U.S. 46, 49-50 (1990) (per curiam), and *United States* v. *Griffith*, 334 U.S. 100, 107 (1948), are inapposite and why no presumption of illegality should apply.

Indeed, there is no limiting principle to the Government's rule. Virtually any patent settlement

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[10] The Government ignores entirely that many so-called reverse-payment settlements, such as those at issue here, actually allow for generic entry years prior to patent expiration. Although the Government notes that the scope-of-the-patent test permits deferral of generic entry until the end of the patent term, Pet. Br. 43 n.10, this does not justify disregarding the fact that these settlements can—and do—allow for assured generic entry prior to patent expiration.

could be characterized as involving a "payment" to the alleged infringer under the Government's approach, opening the floodgates to antitrust litigation. Consider the example of a settlement negotiation over a royalty-bearing license. If a settlement occurs in 2013, and the patent expires in 2023, the patent holder could offer an entry date in 2016 with a 7% royalty, or instead a later entry date in 2018 with a 5% royalty. Would the later entry date with the lower royalty rate constitute a "payment" to move the generic to accept the later date? Indeed, even a royalty-free license could be considered a windfall to the generic/licensee if a "fair" royalty would have been higher. *See also* Section I.C., *infra* (discussing ambiguity in Government's proposed *prima facie* case).[11]

For all of these reasons, the Government has fallen short of establishing that an exceptional "quick look" analysis is warranted for the settlements of patent litigation that include (i) a non-immediate generic entry date and (ii) something that the Government deems a "payment" from the patentee.

C. The Elements of the Government's "*Prima Facie*" Case are Fundamentally Flawed.

The FTC has for many years branded "reverse-payment" settlements as "pay-for-delay." *E.g.*, 2010

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[11] The Government says that its rule applies at least to direct payments, and that the Court need not now decide the rule's applicability to "alternative arrangements" having "parallel" "economic realities." Pet. Br. 36 n.7. However, the FTC already has urged an expansive interpretation of the term "payment." See Section I.C., *infra*. Moreover, here the FTC is not alleging simply a "payment" but rather a purported *over*-payment for serv

FTC Report. Its proposed *prima facie* case, however, requires the antitrust plaintiff to prove neither "payment" nor "delay" before a settlement is declared presumptively illegal. Rather, disproving these elements is left to defendants, who bear the burden of proving their own innocence.

The proposed *prima facie* test requires a plaintiff to show the existence of a "reverse-payment" agreement. Pet. Br. 37. The Government defines such an agreement as one whereby "a patentee (the brand-name manufacturer) agrees to pay an accused infringer (its would-be generic competitor), and the competitor agrees that it will not enter the market for a specified period of time." *Id.* 2. The elements are highly ambiguous and would lead to confusion.

1. The Government asserts that its test applies only to Hatch-Waxman patent litigation settlements that are accompanied by a "payment." *Id.* 16. Yet the Government is remarkably vague on what counts as a "payment," even though it is the "payment" that renders the litigation settlement presumptively anticompetitive under the antitrust laws, causing the burden to shift to the defendants.

At one point the Government's brief mentions a "monetary payment," *id.* 16; at another point it references "money *or similar consideration*," *id.* 27 (emphasis added); and in a footnote it asserts that the rule could also apply to "an alternative form of consideration" having similar effects to "direct payments." *Id.* 36 n.7 (citing C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 663-66 (2009), which describes a broad array of transactions that might supposedly

"disguise the fact of payment"). The Government fails to mention that (i) the FTC *in this case* urged adoption of its presumptive illegality rule "whenever the patent holder provides economic value to the challenger *in any form* in connection with delayed entry," FTC Pet. for Reh'g En Banc 13, *Watson Pharms.*, No. 10-12729-DD (11th Cir. filed June 11, 2012) (emphasis added); and (ii) the FTC recently characterized as a "reverse-payment" an agreement unaccompanied by *any* direct cash payment. *See* Brief of FTC as Amicus Curiae 1-2, *In re Lamictal Direct Purchaser Antitrust Litig.*, Doc. No. 89-3, No. 2:12-cv-00995-WHW-MCA (D.N.J. filed Oct. 5, 2012) (brand-name pharmaceutical company's agreement not to launch "authorized generic" during first-filing generic manufacturer's 180-day exclusivity period constitutes a "payment"); *see also* Order at 10, *In re Lamictal*, Doc. No. 105 (D.N.J. filed Dec. 6, 2012) (reading *K-Dur* as limited to cash payments). The broad definition of "payment" urged to the Court of Appeals could ensnare a myriad of types of value transfers, many of a nature that could be extremely difficult to isolate. *See also* pp. 30-31, *supra* (discussing royalty negotiations).

The present case demonstrates the difficulties with the Government's amorphous standard. Here the Government asserts that it adequately alleged a "payment" by alleging that "Solvay agreed to make payments to Watson (starting at approximately $19 million during the first year of their agreement in 2006 and rising to more than $30 million annually by 2015)." Pet. Br. 56. Under the Government's view, this allegation would suffice to render the settlement agreement presumptively unlawful under the antitrust laws, and shift the burden to *respondents* to

disprove the (presumed) anticompetitive effects. Pet. Br. 17.

Here, however, the Complaint does not allege that money changed hands at the time of Watson's settlement or that any "valuation" was ever agreed by the parties. Rather, Watson entered into a second agreement at the same time as the settlement agreement, providing that Watson would perform promotional services for Solvay in connection with AndroGel, *i.e.*, a specified number of sales calls ("details") to urologists. Complaint ¶¶ 64, 66, J.A. 46. These are services of a nature that this Court recently recognized as having value. *See Sorrell* v. *IMS Health, Inc.*, 131 S. Ct. 2653, 2658 (2011) ("many listeners find detailing instructive"). The Government's actual allegation is that Watson received *disguised* compensation in the form of an alleged *over*payment for co-promotion services. Complaint ¶ 82, J.A. 51. However, in the Government's view, it—or any antitrust plaintiff—need not attempt to isolate any net payment, as opposed to compensation for *bona fide* services at fair market value, in order to make out a *prima facie* case. The mere fact of *any* transfer of value is enough to presume the agreement unlawful, shift the burden to the defendants, and move the case into discovery. *See* Pet. Br. 17 (the "principal means of rebuttal would be through proof that the payment was instead consideration for unrelated property or services.").

To ascertain whether the value provided to the generic manufacturer was really payment for delay, an antitrust court would necessarily have to determine what the "fair" or "appropriate" value of the associated business deal should have been. *Cf. Pac.*

Bell Tel. Co. v. *linkLine Commc'ns*, 555 U.S. 438, 452 (2009) (courts are "ill-suited to act as central planners, identifying the proper price, quantity, and other terms of dealing") (internal quotation marks omitted). Should the antitrust court (or jury) determine that the defendants failed to meet their burden, finding the business deal to have been "richer" than it should have been, under the Government's proposed rule the defendants would, without more, be subject to treble-damage antitrust liability and Government enforcement.

2. The second element of the Government's confused *prima facie* test relates to the agreed generic entry date: the plaintiff must show that "the [generic] competitor agrees that it will not enter the market for a specified period of time." Pet. Br. 2. In contrast, the Third Circuit's *K-Dur prima facie* case requires a showing that "a generic patent challenger [has] agree[d] *to delay* entry[.]" *K-Dur*, 686 F.3d at 218 (emphasis added). The distinction is subtle, but critical to an adequate allegation of anticompetitive effects.

According to the Government, its Complaint stated this second element with the allegation that respondents Watson and Par/Paddock agreed to an entry date nine years in the future. Pet. Br. 56. Evidently, the Government believes its *prima facie* test is satisfied upon a simple showing of a future agreed generic entry date, without reference to when the generic manufacturer might *actually* have entered the market in the absence of a settlement, or even when entry would have occurred in a hypothetical "entry-date-only" settlement. The supposedly anticompetitive effect—*i.e.*, *delayed* generic entry—is thus

uncoupled entirely from the *prima facie* showing of a presumptively unlawful antitrust violation under the Government's test.[12]

In short, permitting a plaintiff to state a *prima facie* case of "payment" without demonstrating an actual net value transfer, and of "delay" with the simple allegation that the parties agreed that generic entry would occur at some date in the future, not only unmoors the *prima facie* case from the competitive effects inquiry, but also sets an alarmingly low—and speculative—bar for pleading an antitrust violation.

D. The Government's Limitation on Defendants' Ability to Rebut the Presumption of Delay Would Result in a Rule with *Per Se* Effect.

As set out in the foregoing discussion, because the presumption is improper, the burden should not be on defendants to prove their innocence by disproving a (presumed) payment. However, even were the burden appropriately shifted to the defendants, the limitations the Government seeks to place on the defense imbues the rule with *per se* effect.

Under the Government's proposed rule, once an antitrust plaintiff has made out the simple *prima facie* case of a "payment" to the generic manufacturer

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[12] While the Third Circuit's requirement that "a generic patent challenger [has] agree[d] to delay entry" may avoid this problem with the Government's formulation, it raises a host of nettlesome questions: How is "delay" determined? What is the starting point? Must a court (or jury) determine when the generic manufacturer otherwise would have entered the market? How does one assess such an entry date in light of the vagaries of litigation?

and a non-immediate entry date, the agreement is presumed to be illegal and the burden shifts to the defendants. The defendants then have the "opportunity" to show that (1) "'any money that changed hands was for something other than a delay,'" Pet. Br. 37 (quoting *K-Dur*, 686 F.3d at 218), such as for "the generic manufacturer's provision of property or services unrelated to the brand-name manufacturer's monopoly," (2) the payment was commensurate with "litigation costs that the brand-name manufacturer avoided by settling," *id.* 37-38; or (3) other "unusual business or litigation justifications" which are "likely rare." *Id.* 38. The Government concludes that "in general defendants should be fully heard on each of their 'proffered justifications.'" *Id.* 39 (citing *NCAA*, 468 U.S. at 113).

Though the Government *says* that defendants should be fully heard on each of their proffered justifications, *ibid.*, rebutting the presumption of delay is apparently not one of these. *Id.* 37-38. Indeed, the Government would now bar inquiry into how the patent litigation might have ended, had it been litigated to conclusion, asserting variously that a patent merits inquiry is "inappropriate," "cumbersome," "doctrinally anomalous," and "likely unworkable in practice." *Id.* 53, 54-55.[13] In other words, under the

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[13] The Government's position on patent merits is remarkable for several reasons. *First*, the FTC's own Complaint includes the "key allegation," Pet. App. 3a, that the patent holder was "not likely to prevail" in the patent suit. Complaint ¶ 86, J.A. 53. *Second*, the California district judge initially hearing this case understood the FTC to have "admitted . . . that it could not litigate this case without also including a theory of competitive harm that would necessitate looking to the merits of the patent cases." *Watson*, 611 F. Supp. 2d at 1088. *Third*, despite reject-

Government's approach, defendants cannot justify their settlement on the basis of the patent. *Cf. NCAA*, 468 U.S. at 103 (a "fair evaluation of [the restraints'] competitive character requires consideration of [defendants'] justifications for them"); *FTC* v. *Ind. Fed'n of Dentists*, 476 U.S. 447, 459-60 (1986) (reviewing proffered justifications); *Nat'l Soc'y of Prof'l Eng'rs* v. *United States*, 435 U.S. 679, 693-96 (1978) (same). Restricting the defendants' defense in this way renders the FTC's test a rule with *per se* effect.

An example helps to illustrate the problem with the Government's approach. Suppose an antitrust plaintiff has alleged and demonstrated that some form of consideration was provided to the generic manufacturer as compensation for a business agreement. Suppose the defendants are unable to show conclusively that the business agreement is at fair market value. At that point, in the face of treble-damage liability, the defendants must also have the ability to disprove the presumption of anticompeti-

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ing a patent-merits inquiry at the liability phase, the Government nevertheless concedes that "[q]uantification of damages in a private antitrust action might require an assessment of what sequence of events would likely have ensued in the absence of a reverse payment." Pet. Br. 55 n.11. But this raises the question of why an inquiry that would be "cumbersome" and "inappropriate" in a case involving injunctive relief would be any less so in a private antitrust treble-damages action. *Fourth*, in contrast to its position here, DOJ recently (and repeatedly) took the position that the "relative likelihood of success of the parties' claims" should be considered. *Schering* U.S. Br. 11; Brief for United States as Amicus Curiae, *Joblove* v. *Barr Labs.*, 551 U.S. 1144 (2007) (No. 06-830), 2007 WL 1511527, at *12 (rule of reason requires considering "the strength of the patent as it appeared at the time at which the parties settled").

tive effects through an objective determination of the likely outcome of the patent litigation. After all, the "reality of patent litigation and risks it presents to the patent holder" are "precisely why a party is likely to choose to settle a patent dispute even if it might well prevail." Pet. App. 31a. But the Government now would deny defendants such an opportunity, apparently in recognition of the "turducken" judicial complexity that would necessarily result.[14]

The lack of authority for the Government's rule, the uncertainty created by its presumption of illegality, and the very real potential for relitigation of the patent case to avoid treble-damages exposure would have tremendous social costs.

E. Adoption of the Government's Test Would Result in Unintended Consequences.

Were this Court to adopt the Government's test for "reverse-payment" settlements, a number of unintended consequences would result.

1. The Government's brief focuses entirely on the purported short-term consumer interest, turning a blind eye to long-term consumer harm that would result from its overly restrictive rule. A rule that too severely restricts settlement options will chill settlements and result in continued litigation. *See Williams* v. *First Nat'l Bank*, 216 U.S. 582, 595 (1910) ("Compromises of disputed claims are favored by the courts[.]"); *Tamoxifen*, 466 F.3d at 212 n.26 (a rule

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[14] An objective inquiry into patent merits, rather than an "*ex ante*" inquiry into the parties' subjective views of the likely outcome of the patent litigation, would be required to ascertain the patent's *actual* exclusionary effect.

making patent litigation settlements "subject to the inevitable, lengthy and expensive hindsight of a jury as to whether the settlement constituted a 'reasonable' restraint" "would place a huge damper on such settlements contrary to the law . . . that settlements are not only permitted, they are encouraged."); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 529 (E.D.N.Y. 2005) ("[M]aking the legality of a patent settlement agreement, on pain of treble damages, contingent on a later court's assessment of the patent's validity might chill patent settlements altogether."), *aff'd*, 544 F.3d 1323 (Fed. Cir. 2008). The uncertainty flowing from such a rule could well lead to fewer Paragraph IV ANDA challenges and reduced incentives to innovate—surely not the FTC's intended outcome.

a. Paragraph IV litigation requires a substantial commitment of resources, which must be considered in the earliest stages of developing any generic drug; in other words, well in advance of any ANDA filing. If, unlike in other litigation, there is no meaningful settlement option and the only possibility is drawn-out, expensive, uncertain litigation to final judgment, generic companies may well decide, in the face of potentially catastrophic treble-damages exposure and exorbitant litigation costs, not to file Paragraph IV ANDAs.[15]

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[15] *See* Bret Dickey & Daniel Rubinfeld, *Would the* Per Se *Illegal Treatment of Reverse Payment Settlements Inhibit Generic Drug Investment?*, 8 J. Comp. L. & Econ. 615, 619-20 (2012) ("[I]f antitrust policy towards patent settlements reduces the ability of generic manufacturers to settle litigation and therefore increases the cost and risk associated with bringing a generic version to market, generic manufacturers' investments

A Paragraph IV certification is not a conclusive determination of invalidity or non-infringement by the PTO or any court. *Cf.* Pet. Br. 5, 18, 43-44. Rather, it represents a generic manufacturer's good-faith assertion that "in the opinion of the applicant and to the best of its knowledge," the patent is invalid and/or not infringed, 21 U.S.C. § 355(j)(2)(A)(vii), and it is an invitation to litigation over precisely this point. *Caraco Pharm. Labs., Ltd.* v. *Novo Nordisk A/S*, 132 S. Ct. 1670, 1677 (2012) ("Filing a paragraph IV certification means provoking litigation.").

Nevertheless, the Government hails the possibility that "in some paragraph IV litigation that might otherwise have been settled through reverse-payment agreements, a rule discountenancing reverse payments may cause the parties to litigate to judgment." Pet. Br. 40. It applauds this result because "in the aggregate, those judgments on the merits will reflect results more in keeping with the policies of the antitrust laws, the Patent Act, and the Hatch-Waxman Amendments than if all the cases had been settled with reverse payments." *Id.* This

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in these challenges are likely to be diminished"); Dickey, Orszag, & Tyson at 398 ("[r]estricting the range of settlement options will reduce the ability of generic manufacturers to settle these cases and increase the cost and risk of bringing a generic drug to market," which "[o]n the margin, . . . will lower the incentives for generic pharmaceutical manufacturers to challenge patents in the first place" and can have a "[substantial] collective impact on future generic competition"); *Asahi Glass Co.* v. *Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) ("A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive.").

view requires acceptance of two interrelated policy positions: (1) forcing parties to litigate to conclusion when they would rather settle is in the public interest; and (2) forcing such litigation is preferable to a settlement accompanied by a "reverse-payment," even though that settlement might well have permitted *more* competition (guaranteed early entry) than the litigation outcome (a win by the patentee).

Nothing in Hatch-Waxman or the Patent Act evidences a congressional intent to *require* Paragraph IV patent litigants to litigate their cases to conclusion, that is, to conscript generic manufacturers as "unwilling private attorneys general." *Cipro*, 363 F. Supp. 2d at 532; *accord Tamoxifen*, 466 F.3d at 202-03. Nothing in the antitrust laws requires pharmaceutical manufacturers to channel funds into litigation that might otherwise be invested in developing other products.

Nor does adoption of a policy discouraging settlement square with the fact that antitrust law is generally leery of rules that might chill procompetitive conduct. *United States* v. *U.S. Gypsum Co.*, 438 U.S. 422, 441 (1978) ("[S]alutary and procompetitive conduct . . . might be shunned by businessmen who chose to be excessively cautious in the face of uncertainty. . . ."); *Am. Needle, Inc.* v. *Nat'l Football League*, 130 S. Ct. 2201, 2209 n.2 (2010) (expressing concern over deterring "perfectly competitive conduct by firms that are fearful of litigation costs and judicial error").

To the extent the Government purports to base its presumption of illegality on the public policy concern over weeding out "voidable" or weak patents, *e.g.*, Pet. Br. 7, 48, this is a red herring. An antitrust rule of

presumptive illegality, with its potential for treble-damage liability, is not the appropriate mechanism for addressing this concern. First, as this Court recently observed, Congress has acted by "amend[ing] the patent laws to account for concerns about 'bad' patents, including by expanding the reexamination process to provide for *inter partes* proceedings." *Microsoft Corp.* v. *i4i P'ship*, 131 S. Ct. 2238, 2252 (2011). Second, an antitrust court reviewing a reverse-payment settlement would ordinarily not be in a position to declare a patent invalid or not infringed; it would typically only decide the question of whether the settlement of the patent litigation violates the antitrust laws. Third, under the Government's framework, even an entry-date-only settlement could involve what the Government views as a supposedly "weak" patent, preserving exclusivity longer than what a decision on the merits might have "warranted."

As to the Government's repeated invocation of the alignment of interests between generic manufacturers and consumers as a basis for its rule (*e.g.*, Pet. Br. 16, 23, 28, 29, 35-36), patent litigants have no duty to agree to terms that, in the view of the FTC, will provide consumers with the *most* competition:

> This concept of a public property right . . . does not translate well into the realities of litigation, and there is no support in the law for such a right. There is simply no legal basis for restricting the rights of patentees to choose their enforcement vehicle (*i.e.*, settlement versus litigation). Equally important, there is no duty to use patent-derived market power in a

> way that imposes the lowest monopoly rents on the consumer.

Cipro, 363 F. Supp. 2d at 531-32 (citing, *inter alia*, *Bement*, 186 U.S. at 91).

b. In addition to disincentivizing generic manufacturers from filing Paragraph IV ANDA challenges, the Government's rule would dampen innovation. Even the Government's brief recognizes the importance of "preserv[ing] the incentives to innovate that benefit consumers in the long run," Pet. Br. 45; yet it proposes a rule that would have the opposite effect. *See Tamoxifen*, 466 F.3d at 203 ("Rules severely restricting patent settlements might also be contrary to the goals of the patent laws because the increased number of continuing lawsuits that would result would heighten the uncertainty surrounding patents and might delay innovation."); *Schering*, 402 F.3d at 1075 ("the caustic environment of patent litigation may actually decrease product innovation by amplifying the period of uncertainty around the drug manufacturer's ability to research, develop, and market the patented product or allegedly infringing product"); Bernard & Tom at 618 ("'[a]n antitrust policy that reduced prices by 5 percent today at the expense of reducing by 1 percent the annual rate at which innovation lowers the cost of production would be a calamity. In the long run a continuous rate of change, compounded, swamps static losses.'") (quoting Frank H. Easterbrook, *Ignorance and Antitrust*, in *Antitrust, Innovation, and Competitiveness*, 119, 122-23 (Thomas M. Jorde & David J. Teece eds., 1992)).

2. The Government's rule also would impose a significant and unwarranted burden on the judicial

system. As noted in Section I.C., *supra*, the Government's proposed *prima facie* test sets an extraordinarily low bar for pleading an antitrust violation. Coupled with the presumption of illegality and shifting of the burden to defendants, the Government's approach provides a sizeable incentive for private plaintiffs to file questionable antitrust suits in hopes of proceeding into discovery and extracting a settlement.

This Court has recognized that "proceeding to antitrust discovery can be expensive," and the importance of "avoid[ing] the potentially enormous expense of discovery in cases with no reasonably founded hope that the discovery process will reveal relevant evidence to support a [Section] 1 claim." *Bell Atl. Corp.* v. *Twombly*, 550 U.S. 544, 558-59 (2007) (internal quotation omitted); *Asahi*, 289 F. Supp. 2d at 995 ("[S]ome threshold of plausibility must be crossed at the outset before a patent antitrust case should be permitted to go into its inevitably costly and protracted discovery phase"). For those antitrust cases that continue past discovery, either courts will be faced with relitigation of the merits of the patent suit that the parties had hoped to resolve through settlement, or defendants will be deprived of a necessary tool for a just and appropriate result. Pet. App. 33a (recognizing the "heavy burdens" that relitigation of the patent merits would impose on courts, a burden that "[o]ur legal system can ill afford").

Nor should the Court overlook the Eleventh Circuit's additional concern regarding review of patent cases by the regional circuits: "Congress has given [the Federal Circuit] exclusive jurisdiction over pa-

tent cases"; because "[the Eleventh Circuit] and the other non-specialized circuit courts have no expertise or experience in this area," they are "ill-equipped to make a judgment about the merits of a patent infringement claim, which is what we would have to do in order to decide how likely the claim was to prevail if it had been pursued in the end." Pet. App. 34a-35a.

Finally, the Government's rule would thwart the established judicial policy favoring settlement. *See McDermott, Inc.* v. *AmClyde*, 511 U.S. 202, 215 (1994); *see also* Section II.A.1., *infra*.

For all of these reasons, the Court should decline to adopt the presumption of illegality urged by the Government.

II. The Scope-of-the-Patent Approach Reflects the Correct Interpretation of Patent Law, Antitrust Law, and the Law of Settlement.

The correct antitrust analysis of patent litigation settlements that are accompanied by a payment from the brand-name manufacturer to the generic manufacturer is the so-called "scope-of-the-patent" approach adopted by the Eleventh, Second, and Federal Circuits. *See* Pet. App. 1a-36a; *Tamoxifen*, 466 F.3d at 212-13; *Cipro*, 544 F.3d at 1333. Under that clear and straightforward approach, "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement" does not violate the antitrust laws "so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." Pet. App. 28a.

A. The Scope-of-the-Patent Approach Appropriately Evaluates the Exclusionary Rights of Patent Holders and the Antitrust Laws.

This Court has long recognized that "[t]he essence of a patent grant is the right to exclude others from profiting by the patented invention." *Dawson*, 448 U.S. at 215; *see also* 35 U.S.C. § 154(a)(1); Section I.A., *supra*. Given this exclusionary right, this Court has repeatedly recognized that a patentee does not face antitrust liability so long as it operates within the zone of its patent. *See, e.g.*, *Walker Process*, 382 U.S. at 177 ("A patent . . . is an exception to the general rule against monopolies.") (internal quotation marks omitted); *Line Material*, 333 U.S. at 300; *Gen. Elec. Co.*, 272 U.S. at 485, 489. Antitrust liability may, however, potentially attach when the patent holder (i) exceeds the bounds of his patent monopoly, *Singer*, 374 U.S. at 196-97; (ii) engages in sham litigation to enforce the patent, *PRE*, 508 U.S. at 60-61; or (iii) has obtained the patent through fraud on the PTO. *Walker Process*, 382 U.S. at 177.

1. Consistent with these considerations, the Court of Appeals recognized that, in an antitrust analysis of a patent litigation settlement, "[t]he patent ma[kes] all the difference" given the patent holder's "lawful right to exclude others." Pet. App. 17a (internal citation omitted); *accord Cipro*, 544 F.3d at 1333 (finding "no error" in the district court's analysis where it had "simply recognized that any adverse anticompetitive effects within the scope of the [] patent could not be redressed by antitrust law").

Given that the '894 patent gave respondent Solvay the right to exclude competition at the time of

the settlement, and the legality of the settlement must be adjudged as of the time the parties entered into the agreement, the Eleventh Circuit correctly treated the patent holder as having the exclusionary right at that time. Pet. App. 20a. In light of the risks of litigation, it is of course reasonable for the parties to settle to eliminate that risk. Indeed, in this case, the FTC's position—that the settlement was unlawful because Solvay was "less likely" to prevail—would have meant that the settlement would have been inappropriate even if Solvay's chances had been "49% to 51%." *Id.* 31a. As the Court of Appeals concluded, in view of the vagaries of litigation, settlement of drug patent litigation "is not a violation of the antitrust laws" when the applicable three conditions are met. *Ibid.*

It is incorrect to treat a presumptively valid patent as having "*no* exclusionary potential if its holder was not likely to win the underlying infringement suit." Pet. App. 29a (emphasis in original). Such an argument "equates a likely result (failure of an infringement claim) with an actual result," when it is "simply not true that an infringement claim that is 'likely' to fail actually will fail." *Id.* 30a. Where the antitrust laws permit resolution of patent litigation through settlement, *Standard Oil*, 283 U.S. at 171, and the patentee does not seek to obtain rights beyond those contemplated in his exclusionary grant, *Line Material*, 333 U.S. at 300, *Gen. Elec. Co.*, 272 U.S. at 485, 489, there is no basis in antitrust law to prohibit the settlement. This was the conclusion reached by the Eleventh, Federal, and Second Cir-

cuits. Pet. App. 28a; *Cipro*, 544 F.3d at 1333; *Tamoxifen*, 466 F.3d at 205.[16]

This Court's antitrust precedent and settled patent law principles clearly look to the bounds of the patent monopoly as the line of demarcation between conduct that is lawful and conduct that may be suspect. Whether the scope-of-the-patent approach is viewed as a structured application of the rule of reason in this context, or instead as a recognition that antitrust law simply does not reach a final settlement of *bona fide* litigation over a *bona fide* patent where the settlement terms remain within the patent's exclusionary potential, the outcome is the same:

> in cases such as this, wherein all the anticompetitive effects of the settlement agreement are within the exclusionary power of the patent, the outcome is the same whether the court begins its analysis under antitrust law by applying a rule of reason approach to evaluate the anti-competitive effects, or under patent law by analyzing the right to exclude afforded by the patent. The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of

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[16] The Sixth Circuit has not expressly adopted a standard for analyzing Hatch-Waxman patent settlements; while it rejected one settlement as illegal, that settlement's terms exceeded the scope of the patent. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 n.13 (6th Cir. 2003); *see also* Brief for United States as Amicus Curiae, *Andrx Pharms, Inc.* v. *Kroger Co.*, 543 U.S. 949 (2004) (No. 03-779), 2004 WL 1562075, at *13-14 (restraints in *Cardizem* "extended beyond the legitimate scope of the patent claims"); *Andrx Pharms, Inc.* v. *Biovail Corp., Int'l*, 256 F.3d 799, 815 (D.C. Cir. 2001) (addressing same agreement as *Cardizem*).

> the patent. This analysis has been adopted by the Second and the Eleventh Circuits . . . and we find it to be completely consistent with Supreme Court precedent.

Cipro, 544 F.3d at 1336 (citing *Walker Process*, 382 U.S. at 175-77). Thus, the scope-of-the-patent approach can be viewed as a structured rule-of-reason inquiry whereby the court, upon finding that the settlement's terms do not exceed the patent's exclusionary scope, may deem the agreement reasonable and lawful.[17]

The scope-of-the-patent approach's easily discernible demarcation between lawful and potentially unlawful conduct adheres to this Court's concern that antitrust rules be clear and explainable. *See linkLine*, 555 U.S. at 452 ("[w]e have repeatedly emphasized the importance of clear rules in antitrust law."); *accord Town of Concord* v. *Bos. Edison Co.*, 915 F.2d 17, 22 (1st Cir. 1990) (antitrust rules "must be clear enough for lawyers to explain them to clients" and "must be designed with the knowledge that firms ultimately act, not in precise conformity with the literal

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[17] In many contexts, it is well-established that a structured rule-of-reason approach is appropriate—*i.e.*, if certain conditions are satisfied, then the rule of reason is also satisfied. *See, e.g.*, *PSKS, Inc.* v. *Leegin Creative Leather Prods., Inc.*, 615 F.3d 412, 418 (5th Cir. 2010) ("a market power screen is [] compatible with *Leegin* and our precedent and that of our sister circuits") (citing *Leegin*, 551 U.S. 877); *Valley Liquors, Inc.* v. *Renfield Imps., Inc.*, 822 F.2d 656, 667-69 (7th Cir. 1987) (applying market share screen); *Assam Drug Co.* v. *Miller Brewing Co.*, 798 F.2d 311, 315-16 (8th Cir. 1986) ("courts have narrowed the [necessary] unlimited inquiry" of the rule of reason by "requiring at the threshold . . . [proof of] defendant's substantial market power in a relevant market").

language of complex rules, but in reaction to what they see as the likely outcome of court proceedings"). The scope-of-the-patent approach provides Hatch-Waxman litigants with a bright-line metric for determining the legality of their conduct at the time of settlement.

The need for clear rules is magnified where the agreements subject to antitrust scrutiny are entered to resolve inherently uncertain patent litigation. *Whitmore* v. *Arkansas*, 495 U.S. 149, 159-60 (1990) ("It is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in this case."); Pet. App. 31a ("[p]atent litigation can also be a high stakes, spin-the-chambers, all or nothing undertaking"); *Asahi*, 289 F. Supp. 2d at 993 ("No one can be *certain* that he will prevail in a patent suit.").

Finally, the scope-of-the-patent approach is consistent with this Court's long-standing view that "public policy wisely encourages settlements." *McDermott*, 511 U.S. at 215; *see also id.* at 215 n.22 ("less than 5% of cases filed in federal court end in trial," and "the bulk of [] nontrial terminations reflect settlements"); *Williams*, 216 U.S. at 595. This policy is fully applicable to patent litigation. *Schering*, 402 F.3d at 1072, 1075 (the general policy favoring settlements "extends to the settlement of patent infringement suits," and "[t]here is no question that settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation."); *Flex-Foot* v. *CRP, Inc.*, 238 F.3d 1362, 1369 (Fed. Cir. 2001) ("[W]hile the federal patent laws favor full and free competition in the use of ideas in the public domain over the technical re-

quirements of contract doctrine, settlement of litigation is more strongly favored by the law."); *Asahi*, 289 F. Supp. 2d at 991 ("The general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits.").

2. The Government's arguments against the scope-of-the-patent approach are unavailing.

a. The Supreme Court precedent cited by the Government in opposition to the scope-of-the-patent approach is either entirely consistent with that approach or inapposite.

Because *Palmer*, 498 U.S. 46, and *Griffith*, 334 U.S. 100, do not address the exclusionary rights inherent in a patent grant, they are inapposite.

Several of the Government's cases relate to attempts to extend the patent monopoly beyond the patent grant; these are consistent with the scope-of-the-patent approach. *See United States* v. *Masonite Corp.*, 316 U.S. 265, 277, 278-79 (1942) (patentee cannot impose restrictions on patented item once it has passed beyond the bounds of the patent monopoly; "the owner of a patent cannot extend his statutory grant by contract or agreement. A patent affords no immunity for a monopoly not plainly or fairly within its grant."); *Line Material*, 333 U.S. at 311 ("no case of this Court has construed the patent and [antitrust] statutes to permit separate owners of separate patents by cross-licenses or other arrangements to fix the prices to be charged by them and their licensees for their respective products."); *United States* v. *U.S. Gypsum Co.*, 333 U.S. 364, 400-01 (1948) (despite the "assumed legality of each separate patent license,"

patents "grant no privilege to their owners of organizing the use of those patents to monopolize an industry through price control, through royalties for the patents drawn from patent-free industry products and through regulation of distribution"); *United States* v. *New Wrinkle, Inc.*, 342 U.S. 371, 379-80 (1952) (because "[p]rice control through cross-licensing [is] barred as beyond the patent monopoly," "[a]n arrangement . . . made between patent holders to pool their patents and fix prices on the products for themselves and their licensees . . . plainly violate[s] the Sherman Act."); *Singer*, 374 U.S. at 189, 193-94 (patentee had "engaged in a series of transactions with [two of its competitors] for an illegal purpose, i.e. to rid [themselves] of infringements by their common competitors"; patentee's agreement to enforce patent to benefit all three parties and exclude foreign competitors constituted an arrangement that "the Sherman Act will not permit").

Two other precedents, moreover, relate to a licensee-plaintiff's ability to challenge the validity of the patent under which it is licensed even though it has agreed not to do so. *Lear, Inc.* v. *Adkins*, 395 U.S. 653 (1969); *Pope Mfg. Co.* v. *Gormully*, 144 U.S. 224 (1892). Nothing in those cases stands for the proposition that an alleged patent infringer *must* litigate its patent challenge to a final judgment, when it would prefer to settle.[18]

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[18] Other cases cited by the Government are similarly unavailing. *See Precision Instrument Mfg. Co.* v. *Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945) (involving perjury in obtaining patent; emphasizing public policy against assertion of patent claims infected by fraud); *Blonder-Tongue Labs., Inc.* v. *Univ. of Ill. Found.*, 402 U.S. 313, 343 (1971) (Court has "condemned

b. The Government also seeks to characterize reverse-payment settlements as anomalous, contending that "[p]ayments from patentees to accused infringers (or from defendants to plaintiffs more generally)[19] are not a traditional settlement term." Pet. Br. 29.[20] The Government disparages as "faulty reasoning" the *Asahi Glass* conclusion that reverse-payment agreements are no different in principle from the "typical settlement." *Id.* 30; *see Asahi*, 289 F. Supp. 2d at 994 (observing that "*any* settlement agreement can be

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attempts to broaden the physical or temporal scope of the patent monopoly"; emphasizing judicial economy concerns in relitigation of patent validity); *Cardinal Chem. Co.* v. *Morton Int'l, Inc.*, 508 U.S. 83, 99-103 (1993) (reiterating judicial economy concerns).

[19] We assume the Government means "from plaintiffs to defendants."

[20] The Government's assertion that reverse-payment settlements do not occur outside the Hatch-Waxman context overlooks that the terms of private settlement agreements are not generally publicly available, nor are most private settlement agreements subject to federal government review—hence the lack of statistics on settlements involving a value transfer to the defendant is not surprising. Such cases do exist. *See, e.g.*, *Metro-Goldwyn Mayer, Inc.* v. *007 Safety Prods., Inc.*, 183 F.3d 10, 13 (1st Cir. 1999); *In Time Prods. Ltd.* v. *Toy Biz, Inc.*, 38 F.3d 660, 662 (2d Cir. 1994); Joris Evers, *Microsoft, Lindows Make a Deal*, PC World (July 19, 2004), www.pcworld.com/article/id,116947-page,1-c,lindowslinspire/article.html ($20 million payment by plaintiff Microsoft to defendant Lindows in settlement of trademark infringement action); Donald Zuhn, *Invitrogen and Agilent Technologies Settle Patent Suits* (Feb. 6, 2008) http://www.patentdocs.org/2008/02/invitrogen-and.html (patent settlement in which defendant agreed to discontinue its product and make a payment in exchange for royalty fees from plaintiff on another patent).

characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement"). But the Government does not argue that the mere *existence* of consideration to the defendant is unusual—indeed it concedes that "any settlement that a defendant accepts presumably affords some benefit that the defendant would not receive if it litigated the suit *and lost*." Pet. Br. 30. Rather, the Government takes issue with the *amount* and nature of the consideration. *Ibid.* Yet as the courts of appeals have held, given the risks at stake, the amount and nature of the payment (let alone its mere existence) do not serve as a reliable indicator of the competitive effects of a patent-litigation settlement agreement. Pet. App. 31a-32a ("[w]hen hundreds of millions of dollars of lost profits are at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.") (internal quotation marks omitted); *Tamoxifen*, 466 F.3d at 208-09 (any suspicion about a reverse-payment "abates upon reflection" for "so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of a patented product").

c. Nor is the scope-of-the-patent approach a rule of *per se* legality; it is incorrect that this approach "gives no meaningful antitrust scrutiny to reverse-payment agreements." Pet. Br. 17. First, a focus on the patent's "potential exclusionary power" does *not* mean that all reverse-payment settlements of patent litigation are immune from antitrust attack: "[a] patent holder and any of its challengers cannot enter

into an agreement that excludes more competition than the patent has the potential to exclude." Pet. App. 20a. To be within the scope-of-the-patent test, the settling parties cannot agree, for example, to defer generic entry beyond the patent term, impose restrictions on products unrelated to the intellectual property rights at issue, or manipulate the generic first-filer's 180-day marketing exclusivity. Similarly, a patentee who sues on a patent it knows is invalid or not infringed, or was obtained by fraud, would be subject to antitrust scrutiny for seeking to obtain more exclusion than the patent grant provides. Pet. App. 28a n.10. The sham and fraud requirements are "not artificial obstacles to recovery," but rather are "essential components of real market injury" in this context. *Brooke Grp. Ltd.* v. *Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 226 (1993). By weeding out agreements that seek to extend the patent's exclusionary potential, the inquiries of (i) sham litigation, (ii) fraud on the PTO, and (iii) conduct beyond the patent's exclusionary potential, reflect the appropriate calibration of the antitrust analysis.

d. Finally, the Government claims that the scope-of-the-patent approach upends the balance that Congress sought to achieve through Hatch-Waxman between encouraging generic entry and incentives for innovation. Pet. Br. 32. Yet when Congress last acted in the Hatch-Waxman sphere, enacting the MMA in 2003, Congress did not implement any provisions outlawing reverse-payment settlements or declaring them presumptively illegal. *See* MMA, Pub. L. No. 108-173, 117 Stat. 2066. In the years since, Congress has repeatedly declined to enact legislation addressing reverse-payment settlements despite the introduction of numerous bills including such a legis-

lative change. *See* H.R. 3995, 112th Cong. (2012); S. 27, 112th Cong. (2011); S. 3677, 111th Cong. § 746 (2010); H.R. 4899, 111th Cong. § 4201 (2010); H.R. 3962, 111th Cong. § 2573 (2009); H.R. 1706, 111th Cong. (2009); S. 369, 111th Cong. (2009); S. 316, 110th Cong. (2007); H.R. 1902, 110th Cong. (2007); H.R. 1432, 110th Cong. (2007); S. 3582, 109th Cong. (2006). A new bill was recently introduced in the Senate, again containing provisions that would render presumptively unlawful a patent litigation settlement where (i) an ANDA filer receives "anything of value"; and (ii) the ANDA filer "agrees to limit or forego research, development, manufacturing, marketing, or sales of the ANDA product for any period of time." S. 214, 113th Cong. (2013). To the extent that a new rule should be applied to reverse-payment settlements, it is Congress that should act, with appropriate legislative attention to the complexities and nuances of new statutory rules.

B. Under the Scope-of-the-Patent Approach, the Complaint Failed to State a Claim.

The FTC's Complaint failed to allege that the settlements' terms exceeded the '894 patent's exclusionary potential. It likewise failed to allege that the '894 patent was procured by fraud. And it failed to allege that Solvay's suits against Watson and Par/Paddock to enforce the patent were shams. Accordingly, the district court properly dismissed the Complaint for failure to state a claim.

CONCLUSION

For the foregoing reasons, the judgment of the Court of Appeals should be affirmed.

Respectfully submitted,

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RESPONDENT'S BRIEF

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FEDERAL TRADE COMMISSION, PETITIONER

v.

ACTAVIS, INC., ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

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QUESTION PRESENTED

This case is about settlements of patent litigation brought under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act). Flaws in the Hatch-Waxman Act, including those relating to settlements concluded thereunder, prompted Congress to enact remedial amendments in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

The settlements in this case involve Abbreviated New Drug Applications (ANDAs) governed by the pre-amendment law, and thus are known in the industry as "pre-MMA" settlements. The United States twice advised this Court that the MMA's remedial changes warranted denying certiorari in cases involving pre-MMA settlements to address antitrust questions concerning reverse payments. Among other changes, the MMA added a specified antitrust penalty and an antitrust savings clause.

The question presented here is the same as stated by the United States when it opposed the FTC's petition for a writ of certiorari in *Schering-Plough Corp.* v. *FTC*, 402 F.3d 1056 (CA11 2005), cert. denied, 548 U.S. 919 (2006):

> Whether the antitrust laws prohibit a brand name drug patent holder and a prospective generic competitor from settling patent infringement litigation by agreeing that the generic manufacturer will not enter the market before a future date within the term of the patent and that the patent holder will make a substantial payment to the generic manufacturer.

U.S. Br. I, *supra* (No. 05-273) (filed May 17, 2006).

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PRELIMINARY STATEMENT AND SUMMARY OF ARGUMENT

The FTC asks this Court to hold that "reverse-payment" patent settlements are presumptively unlawful under "quick-look" antitrust analysis. The FTC contends that such a categorical rule of presumptive unlawfulness "serves the purposes of competition law, patent law, and the Hatch-Waxman Amendments." FTC-Br.19-40. None of those three considerations warrant such categorical departure from the traditional rule of reason.

1. The default analysis for alleged restraints of trade is the rule of reason. *Texaco* v. *Dagher*, 547 U.S. 1, 5 (2006). For patent-based restraints, the rule of reason accounts for statutory, time-limited patent monopolies by first inquiring whether the restraint is within the scope-of-the-patent. *E.g.*, *United States* v. *Line Material*, 333 U.S. 287, 353 (1948) ("If the limitations in a license reach beyond the scope of the statutory patent rights, then they must be tested by the terms of the Sherman Act.").

This Court never has upheld an antitrust claim against patent enforcement or licensing within the scope of a non-sham patent. ("Sham" defined to include fraudulently procured patents.) And, as the FTC concedes, FTC-Br.26-27: "Where there are legitimately conflicting claims or threatened interferences, a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act." *Standard Oil (Indiana)* v. *United States*, 283 U.S. 163, 171 (1931).

Without establishing the other elements under Sherman Act §§1-2, an antitrust claim is *not* established by: (i) enforcing a patent knowingly

procured by fraud, *Walker Process Equip.* v. *Food Mach. & Chem.*, 382 U.S. 172, 174 (1965); or (ii) bringing an objectively baseless patent suit with the improper subjective motivation of interfering with the purported infringer's market-participation, *Prof'l Real Estate Investors* v. *Columbia Pictures* (*PRE*), 508 U.S. 49, 60-61 (1993). The FTC nonetheless asks this Court to hold that a reverse-payment patent-settlement alone establishes a presumptive antitrust violation. FTC-Br.15.

That the FTC's rule disregards statutorily conferred patent monopolies is evident in the FTC's analogizing reverse-payment settlements to the "paradigmatic antitrust violation" of horizontal market-allocation that this Court has condemned as a *per se* violation. FTC-Br.19-20, 23 (citing *Palmer* v. *BRG of Georgia*, 498 U.S. 46 (1990)). Statute expressly authorizes patent-holders to engage in the type of market-allocation in *Palmer*, a case that did *not* involve patents. See 35 U.S.C. 261 ("The applicant, patentee, or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States.").

By ignoring the lawful exclusionary power of patents—and the correspondingly lawful restraints in licenses thereunder—the FTC's *Palmer* analogy and proposed rule incorrectly assume that patent-settlement licenses entail horizontal, rather than vertical, restraints. Ascertaining whether such restraints are horizontal or vertical is impossible without predicting which side would have won the patent litigation:

> [A]ntitrust analysis of intellectual property licensing arrangements examines whether the relationship among the parties to the arrangement is primarily horizontal or vertical in nature, or whether it has substantial aspects of both.
>
> *** [T]he Agencies ordinarily will treat a relationship between a licensor and its licensees, or between licensees, as horizontal when they *would have been* actual or likely potential competitors in a relevant market *in the absence of the license.*

DOJ/FTC Antitrust Guidelines for the Licensing of Intellectual Property §3.3 (1995) (*DOJ/FTC Guidelines*) (emphasis added).

Here, the FTC concedes that basing antitrust analysis on a prediction of which side would have prevailed would be "doctrinally anomalous and likely unworkable in practice." FTC-Br.53. For convenience, the FTC's rule simply deems patent-settlements to be horizontal restraints.

Besides ignoring the patent, the FTC seeks an unprecedented departure from traditional antitrust principles, which assess the lawfulness of *restraints*, to a novel rule that instead assesses the consideration underlying the agreement. In other words, the same restraint may be upheld or condemned under the FTC's rule depending on whether the amount of consideration was minimal or substantial. In 120 years, no antitrust rule has turned on appraising parties' consideration.

Furthermore, the FTC concedes that removing financial consideration as a potential settlement term

will cause fewer cases to settle: "To be sure, in some paragraph IV litigation that might otherwise have been settled through reverse-payment agreements, a rule discountenancing reverse payments may cause the parties to litigate to judgment." FTC-Br.40.

To the FTC, requiring parties "to pursue the course that maximizes competition and consumer welfare accords with basic antitrust norms." FTC-Br.51. But "[a]s a general rule, businesses are free to choose the parties with whom they will deal, as well as the prices, terms, and conditions of that dealing." *Pac. Bell Tel.* v. *Linkline Commc'ns*, 555 U.S. 438, 448 (2009) (citing *United States* v. *Colgate*, 250 U.S. 300, 307 (1919)). And, "[c]ourts are ill suited 'to act as central planners, identifying the proper price, quantity, and other terms of dealing.'" *Id.* at 452 (quoting *Verizon Commc'ns* v. *Law Offices of Curtis V. Trinko*, 540 U.S. 398, 408 (2004)); see *Cont'l T.V.* v. *GTE Sylvania*, 433 U.S. 36, 58 n.29 (1977) ("The location restriction used by Sylvania was neither the least nor the most restrictive provision that it could have used. *** We are unable to perceive significant social gain from channeling transactions into one form or another."), overruling *United States* v. *Arnold, Schwinn & Co.*, 388 U.S. 365 (1967); see also Stephen Breyer, *Regulation and Its Reform* 157 (1982) ("[Antitrust laws] act negatively, through a few highly general provisions *prohibiting* certain forms of private conduct. They do not affirmatively order firms to behave in specified ways; for the most part, they tell private firms what not to do.").

Finally, the FTC's categorical presumption of unlawfulness is doctrinally unsound. This Court's last "quick-look" case rejected the FTC's quick-look at an advertising restriction imposed by a dentists' association, holding: "What is required, *rather*, is an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint." *California Dental Ass'n* v. *FTC*, 526 U.S. 756, 781 (1999) (emphasis added). Even dissenters agreed with this "unobjectionable principle[]." *Ibid.* (Breyer, J., concurring in part and dissenting in part).

Before rejecting quick-look in *California Dental*, the Court had applied it in only three cases:

- *FTC* v. *Indiana Federation of Dentists*, 476 U.S. 447, 458-459 (1986) (evaluating group boycott by dentists' association under quick-look instead of *per se* rule: "[W]e decline to resolve this case by forcing the Federation's policy into the 'boycott' pigeonhole and invoking the *per se* rule.");
- *NCAA* v. *Board of Regents*, 468 U.S. 85, 100-101 (1984) (evaluating broadcasting output-limitation imposed by college football association under quick-look because the "industry [is one] in which horizontal restraints on competition are essential if the product is to be available at all"); and
- *Nat'l Soc'y of Prof'l Eng'rs* v. *United States*, 435 U.S. 679, 692-693 (1978) (evaluating engineers' association's concerted refusal to discuss prices with potential customers under quick-look by "analyzing the facts peculiar to the business, the history of the restraint, and the reasons why it was imposed").

Each time, the Court considered quick-look on an *ad hoc* basis for the circumstances of the alleged restraint (each involving unique justifications proffered by different associations). This Court never has applied a quick-look presumption of unlawfulness to *categories* of restraints prospectively. The *per se* rule applies categorically, and then, only after judicial experience demonstrates that a category of restraint is almost always anticompetitive. Because the FTC's presumption effectively can be rebutted only by proof that there was no "reverse-payment," the FTC is really seeking an unprecedented, watered-down category of *per se* violations.

2. The FTC's purported patent-law justifications for its presumption are unsound. The crux of the argument is that patents confer merely "probabilistic" rights and, because the FTC suspects many "weak" patents exist, patent-settlements require judicial appraisal beyond the scope-of-the-patent:

> [B]ecause the scope-of-the-patent approach assumes (at least once the non-sham threshold has been surmounted) that all patents are equally valid and infringed, it produces *the absurd result that an ironclad patent and a trivial patent have the same exclusionary force.*

FTC-Br.44 (emphasis added) (internal quotation marks omitted); see J.A.38 ¶40 (alleging that PTO examiners labor under "quotas [that] are reinforced by examiners' bonus compensation"); U.S.Br.11, *Schering-Plough*, *supra* ("The FTC's petition emphasizes what it calls the 'probabilistic' nature of the property interest created by the patent laws and

the view that 'a patent is not a right to exclude, but rather a right to *try* to exclude.'") (quoting FTC petition).

This Court recently rejected a similar challenge to the statutory presumption of patent validity, reaffirming challengers' burden of proving invalidity by clear-and-convincing evidence:

> Congress has amended the patent laws to account for concerns about "bad" patents, including by expanding the reexamination process to provide for *inter partes* proceedings. Through it all, the evidentiary standard adopted in [35 U.S.C.] § 282 has gone untouched. Indeed, Congress has left the Federal Circuit's interpretation of § 282 in place despite ongoing criticism, both from within the Federal Government and without.

Microsoft v. *i4i*, 131 S.Ct. 2238, 2252 & n.11 (2011) (citing FTC report advocating preponderance-of-the-evidence standard that the Court rejected); *id.* at 2243 (describing "the basic proposition that a government agency such as the PTO was presumed to do its job").

Nevertheless, the FTC contends: "[T]he scope-of-the-patent approach allows the patentee to purchase the same period of exclusivity that a successful infringement suit would produce, *even if all would concede that the patentee had little likelihood* of *prevailing* in the infringement litigation." FTC-Br.44 (emphasis added). The FTC never explains how to establish this Greek chorus of agreement on the patent's slim chances if the case is *not* "objectively baseless." *PRE*, 508 U.S. at 60-61.

All here agree that attempting a more fine-tuned antitrust assessment of patent merits than *PRE*'s sham standard would be "doctrinally anomalous and likely unworkable in practice." FTC-Br.53. For antitrust purposes, there are no "weak" patents; there are sham patents and non-sham patents.

3. The FTC's final argument for departing from traditional antitrust analysis is that "reverse-payment agreements frustrate the purposes of the Hatch-Waxman Amendments." FTC-Br.30.

First, the FTC contends (without citation) that the "Hatch-Waxman Amendments reflect a strong congressional policy that favors testing the scope and validity of pharmaceutical patents." FTC-Br.30. But no Hatch-Waxman provision favors litigation-to-the-death over settlements, which are critical for generic entry:

> [G]eneric companies are successful, thus able to market the generic product before patent expiration, in just 48 percent of cases [that have gone to trial]. But when factoring in settlements, generics are successful in bringing the generic product to market before patent expiration in 76 percent of cases.

Generic Pharm. Ass'n, *Generic Drug Savings in the U.S.*, at 7 (4th ed. 2012).

Hatch-Waxman's balanced provisions are *not* designed to change the outcomes of pharmaceutical-patent litigation. *Caraco Pharm.* v. *Novo Nordisk*, 132 S.Ct. 1670, 1676 (2012) (explaining Hatch-Waxman's objective "[t]o facilitate the [FDA] approval of generic drugs as soon as patents allow").

Second, the FTC contends that "nothing in the Amendments contemplates that a patentee will pay an accused infringer in order to escape paragraph IV litigation." FTC-Br.31. That statement is literally true because the FTC defines "Amendments" to include only the Hatch-Waxman Act. The statement is misleading, however, because it ignores the MMA Amendments of 2003.

In response to reverse-payment settlements with restraints that *exceeded* patent scope, the MMA Amendments to Hatch-Waxman provided, among other remedial changes: (i) a requirement that patent-settlements be filed with DOJ/FTC; (ii) a specified-antitrust penalty; and (iii) an antitrust-savings clause expressly providing that such agreements are *not* presumed to violate the antitrust laws.

Indeed, due to the MMA's extensive remedial changes, the United States advised this Court *not* to grant certiorari in pre-MMA cases to address antitrust issues involving reverse-payment settlements. U.S.Br.19-20, *Joblove* v. *Barr Labs.*, 551 U.S. 1144 (2007) (No.06-830) (filed May 23, 2007) ("Congress amended the Hatch-Waxman Act to provide for forfeiture of the 180-day exclusivity period ***. [I]t may now be more difficult for a first-filing generic manufacturer to enter into a settlement and then use the 180-day exclusivity period effectively to lock other generic manufacturers out of the market ***."); U.S.Br.18, *Andrx Pharms.* v. *Kroger*, 543 U.S. 939 (2004) (No.03-779) (filed July 9, 2004) ("This Court's review also may be unwarranted in light of certain amendments to the Hatch-Waxman Act that were enacted by Congress in 2003 ***.").

Yet, having lobbied Congress to pass the MMA, the FTC's merits brief oddly ignores the MMA Amendments entirely. It is weird that in an antitrust case concerning Hatch-Waxman settlements, the government does not mention the MMA's remedial changes, which included, *inter alia*, a specified-antitrust penalty and an antitrust-savings clause.

Significantly, unlike the MMA, which did *not* change antitrust standards for reverse-payment settlements, pending legislation proposes the very standard the FTC seeks here. See Preserve Access to Affordable Generics Act, S.214, 113th Cong. (introduced Feb. 4, 2013), Par/Paddock-Br.App.1a-20a.

***

That the United States switched position on the reverse-payment issue since the last administration warrants special mention.

In *Schering-Plough*, the United States opposed the FTC's petition: "The decision below does not conflict with any decisions of this Court ***." U.S.Br.1, *supra*. Respondents settled under *Schering-Plough* in 2006, and the Eleventh Circuit applied *Schering-Plough* in upholding respondents' settlements in this case.

The United States continued: "[T]he public policy favoring settlements, and the *statutory right of patentees to exclude competition within the scope of their patents*, would potentially be frustrated by a rule of law that subjected patent settlements involving reverse payments to automatic or near-automatic invalidation." U.S.Br.10-11 (emphasis

added). As the FTC concedes, that position is irreconcilable with the government's position here: "In those briefs [in 2004, 2006, and 2007], the United States did not endorse the FTC's view that reverse-payment settlements are presumptively anti-competitive." FTC-Br.41 n.9.

The United States' new position is entitled to little deference. See Transcript of Oral Argument at 44, *Kiobel* v. *Royal Dutch Petroleum*, No.10-1491 (Oct. 1, 2012) (Roberts, C.J.) ("[W]hatever deference you are entitled to is compromised by the fact that your predecessors took a different position.").

The Eleventh Circuit's decision here is no less correct than *Schering-Plough*, which the United States stated did "not conflict with any decisions of this Court." U.S.Br.1. (*Palmer* was decided sixteen years before that statement.) Respondents' reliance and repose interests in settlements concluded in 2006 in the Eleventh Circuit, undisputedly in conformity with circuit law, should not depend on the outcome of an election any more than this Court's antitrust jurisprudence should.

4. This case involves two separate settlements. Argument II addresses points applicable only to the settlement between respondents Solvay and Par/Paddock:

> (A) the district court's Consent Judgment and Order of Permanent Injunction currently restrains Par/Paddock's generic entry until 2015, conferring *Noerr-Pennington* immunity; and
>
> (B) the FTC fails to state a claim under any antitrust standard against the Par/Paddock settlement because as a second ANDA-filer under

pre-MMA rules, Par/Paddock could *not* have obtained an earlier settlement-entry date even absent any alleged reverse-payment.

STATEMENT

A. The Hatch-Waxman Act of 1984

The "Drug Price Competition and Patent Term Restoration Act of 1984" had two goals:

1. Drug Price Competition

Congress enacted Hatch-Waxman "[t]o facilitate the approval of generic drugs as soon as patents allow." *Caraco*, 132 S.Ct. at 1676. Hatch-Waxman created the ANDA process, 21 U.S.C. 355, to shorten the FDA's generic-drug approvals. *Eli Lilly* v. *Medtronic*, 496 U.S. 661, 676 (1990). Congress did *not* shorten patent-term or exclusive-sales periods for brand-name drugs. *Id.* at 676-678.

Hatch-Waxman encourages generic manufacturers to seek market-entry and makes pharmaceutical patent-litigation more efficient. Generics can instigate litigation through a "highly artificial act of infringement" without risking treble damages on infringing sales. *Id.* at 678. Brand-names, in turn, can obtain a thirty-month stay on generic marketing while litigating the case. 21 U.S.C. 355(j)(5)(B)(iii). To incentivize generics to file Paragraph-IV ANDAs, the first-to-file obtains 180-day generic exclusivity, 21 U.S.C. 355(j)(5)(B)(iv), which delays other generic entry and maintains higher drug prices.

This balanced scheme is not designed to expedite generic entry at all costs. Rather, Paragraph-IV procedures are "an important new mechanism designed to guard against infringement of patents

relating to pioneer drugs." *Eli Lilly*, 496 U.S. at 676-677. Hatch-Waxman facilitates litigation, but does *not* affect litigation outcomes.

2. Patent Term Restoration

"[T]he 1984 Act was designed to respond to two unintended distortions of the 17-year patent term produced by the requirement that certain products must receive premarket regulatory approval." *Id.* at 669. First, patent terms begin before related drugs clear the FDA's approval process: "[T]he 'clock' on his patent term will be running even though he is not yet able to derive any profit from the invention." *Id.* at 669-670. Hatch-Waxman responded by *extending* patent-holders' exclusive-marketing period up to five years. 35 U.S.C. 156(a); *Eli Lilly*, 496 U.S. at 671.

Second, Hatch-Waxman ended "an effective extension of the patent term" under the requirement that generics wait until patent expiration before beginning FDA's approval process. *Eli Lilly*, 496 U.S. at 670. Hatch-Waxman authorizes generics to use an invention during the patent term "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." 35 U.S.C. 271(e)(1).

Hatch-Waxman thus enabled "generic substitutes on the market as quickly as possible *after the expiration of the patent*." H.R.Rep.No.857, 98th Cong., Pt.2, at 9 (1984) (emphasis added). Congress insisted that patent-holders' exclusive-sales periods remain uncompromised:

> [T]he only activity which will be permitted by the bill is a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute. The patent holder retains the right to exclude others from the major commercial marketplace during the life of the patent. Thus, the nature of the interference with the rights of the patent holder is not substantial.

Id. at 8.

B. The MMA Amendments of 2003

Two features of Hatch-Waxman's Paragraph-IV provisions created incentives for reverse-payment settlements.

First, as the United States explained in a 2007 CVSG, Hatch-Waxman's "highly artificial act of infringement" creates asymmetrical risks between brand-names and generics, incentivizing reverse-payment settlements even when the patent-holder is confident:

> Because the generic manufacturer will not have made infringing sales (that would give rise to claims for damages) or incurred production and marketing costs at the time of the infringement suit, its litigation risk will be minimal, whereas the patent holder faces potentially devastating consequences if it loses the litigation. The resulting disparity in the litigants' respective risks may tend to increase the cost of settlement for a patent holder and make reverse payments more likely, even when the patent holder's legal claims are relatively strong.

U.S.Br.10, *Joblove*, *supra*.

Illustrating this asymmetry, the FTC reports: "[F]or a drug with [annual] brand sales of $130 million, a generic that does not anticipate [authorized generic] competition will expect a patent challenge to be profitable if it has at least a 4 percent chance of winning [a Paragraph-IV challenge]." FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* iii n.7 (2011).

Second, as the United States also explained, Hatch-Waxman's 180-day exclusivity period, designed to incentivize generics by rewarding first-filers, unwittingly enabled first-filer settlements to "bottleneck" subsequent generic entry:

> [T]he 180-day exclusivity period created an incentive for the parties to settle the litigation with a non-entry payment to the generic, under which the generic would delay commercialization of the generic product, thus postponing the commencement of the 180-day exclusivity period and locking other generics out of the market indefinitely.

U.S.Br.11, *Joblove*, *supra*.

The resulting reverse-payment settlements drew FTC attention. *E.g.*, *In re Abbott Labs.*, No.C-3945 ¶37 (F.T.C. May 22, 2000) (administrative complaint); *In re Hoechst Marion Roussel*, No.9293 ¶31 (F.T.C. Mar. 16, 2000) (same).

This enforcement activity led Congress to ask the FTC to study Hatch-Waxman and recommend legislative changes:

> As a result of the cases we brought, Congress granted the FTC the authority to conduct an

> industry-wide study to assess the effectiveness of generic entry under Hatch-Waxman. Based on this study, we made a number of legislative recommendations geared toward facilitating generic entry and thus better achieving the goals of the Hatch-Waxman Act.

Orson Swindle, Commissioner, FTC, *A Regulator's Perspective on Protecting Consumers and Competitive Marketplaces*, Remarks before ABA Section of Administrative Law and Regulatory Practice (Nov. 7, 2003).

Significantly, pre-MMA judicial decisions on reverse-payment settlements concerned agreements with restraints that *exceeded* patent scope and, in particular, provisions prohibiting first-filers from relinquishing 180-day exclusivity. *Valley Drug* v. *Geneva Pharms.*, 344 F.3d 1294, 1311-1313 (CA11 Sept. 15, 2003) (agreement not to relinquish 180-day exclusivity and not to sell certain non-infringing products); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 907-908 (CA6 June 13, 2003) (agreement not to relinquish 180-day exclusivity); *Andrx Pharms.* v. *Biovail*, 256 F.3d 799, 809-810 (CADC 2001) (same).

Neither settlement here includes any restraint outside the scope-of-the-patent.

1. Remedial Changes to Hatch-Waxman

The MMA Amendments of 2003 recalibrated the competitive landscape for Hatch-Waxman litigation and settlements. In particular, "there are two separate exclusivity frameworks—one for first-filed ANDA applications submitted before December 8, 2003 (pre-MMA) and one for first-filed ANDA

applications submitted on or after December 8, 2003 (post-MMA)." *ANDA Litigation: Strategies and Tactics for Pharmaceutical Patent Litigators* 68 (Kenneth L. Dorsney et al. eds., 2012).

First, the MMA added forfeiture provisions that can deprive a first-filer of exclusivity. In a 2007 CVSG, the United States predicted (correctly) that the MMA's elimination of 180-day "bottle-necking" would reduce incentives for reverse-payments:

> Congress amended the Hatch-Waxman Act to provide for forfeiture of the 180-day exclusivity period for various reasons ***. As a practical matter, therefore, it may now be more difficult for a first-filing generic manufacturer to enter into a settlement and then use the 180-day exclusivity period effectively to lock other generic manufacturers out of the market ***.

U.S.Br.19-20, *Joblove*, *supra*.

Second, the MMA added shared-exclusivity provisions, facilitating *multiple* first-filer exclusivity. 21 U.S.C. 355(j)(5)(B)(iv)(II)(bb). In a 2004 CVSG, the United States predicted (again correctly) that this shared-exclusivity amendment would reduce incentives for reverse-payments:

> [A]llowing multiple ANDA applicants to obtain the 180-day exclusivity period[] may increase the transaction costs for pioneer drug companies that seek to enter into agreements with those applicants. On balance, therefore, the 2003 amendments may reduce the number of agreements containing reverse payments.

U.S.Br.18, *Andrx*, *supra*.

In this case, the Eleventh Circuit echoed the competitive significance of multiple challengers:

> If the patent actually is vulnerable, then presumably other generic companies, which are not bound by the first challenger's reverse payment settlement, will attempt to enter the market and make their own challenges to the patent. Blood in the water can lead to a feeding frenzy. Although a patent holder may be able to escape the jaws of competition by sharing monopoly profits with the first one or two generic challengers, those profits will be eaten away as more and more generic companies enter the waters by filing their own paragraph IV certifications attacking the patent.

Pet.App.35a-36a.

Beyond the MMA's new 180-day forfeiture and shared-exclusivity provisions, the FTC recommended five additional remedial changes prompted by its investigation of pre-MMA settlements. Congress enacted all five. See Par/Paddock-B.I.O.7 n.2 (detailing those amendments).

2. The MMA's Specified Antitrust Penalty

Post-MMA, Paragraph-IV settlements and related agreements are filed with DOJ/FTC for antitrust review. 21 U.S.C. 355 note.

Furthermore, Congress specified a penalty for agreements challenged by DOJ/FTC and held to violate the antitrust laws. Tellingly, the penalty is forfeiture of 180-day exclusivity, which applies when:

> The first applicant enters into an agreement with another [ANDA] applicant ***[,] the holder of the application for the listed drug, or an owner of the patent that is the subject of the [Paragraph IV certification], the [FTC] or the [DOJ] files a complaint, and there is a final decision of the [FTC] or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws ***.

21 U.S.C. 355(j)(5)(D)(i)(V); see 355(j)(5)(D)(ii) (providing resulting forfeiture of 180-day exclusivity).

Thus, contrary to the FTC's suggestion that Congress never "contemplate[d] that a patentee will pay an accused infringer in order to escape paragraph IV litigation," FTC-Br.31, Congress contemplated precisely that and specified an antitrust penalty tailored to Congress's primary concern: settlements that restrain the first-filer's use of 180-day exclusivity (thereby exceeding patent scope) to "bottleneck" subsequent generic entry.

3. The MMA's Antitrust Savings Clause

Along with the MMA's provision for DOJ/FTC antitrust review, came an antitrust-specific savings clause:

> **Sec. 1117. SAVINGS CLAUSE.**
>
> Any action taken by the [DOJ] or the [FTC], or any failure of the [DOJ] or the [FTC] to take action, under this subtitle shall not at any time bar any proceeding or any action with respect to any agreement between a brand name drug

> company and a generic drug applicant, or any agreement between generic drug applicants, under any other provision of law, *nor shall any filing under this subtitle constitute or create a presumption of any violation of any competition laws.*

21 U.S.C. 355 note (emphasis added).

Congress thus expressly declined to alter the default, common-law antitrust standard for Hatch-Waxman settlements. See *Astoria Federal Savings* v. *Solimino*, 501 U.S. 104, 108 (1991) ("Congress is understood to legislate against a background of common-law adjudicatory principles."); 2B Singer & Singer, *Statutes and Statutory Construction* §50.1 (7th ed. 2012) ("All legislation is interpreted in the light of the common law and the scheme of jurisprudence existing at the time of its enactment.").

C. Post-MMA, Reverse-Payment Rates Declined; FTC Has Not Challenged Settlements Since.

Post-MMA, the FTC issues annual reports on Hatch-Waxman settlements, including "potential pay-for-delay" settlement statistics. According to the FTC, "settlements potentially involve pay for delay [when] they contain both compensation to the generic manufacturer and a restriction on the generic manufacturer's ability to market its product." *Agreements Filed with FTC under MMA Act of 2003: Overview of Agreements Filed in FY 2012.*

Thus, a settlement that (i) provides for anything other than immediate generic entry (regardless of how long before patent expiration entry is permitted), and (ii) confers any value to the generic beyond early entry constitutes "potential pay-for-delay."

The FTC's FY2004-2011 reports indicate that "potential pay-for-delay" rates peaked at 50% in FY2006, declining to a low of 18% in FY2011.[1]

Because of the time-lag (often several years) between a Paragraph-IV filing and any subsequent litigation settlement, a settlement occurring after the MMA Amendments (in 2006 for example) may still involve a pre-MMA ANDA and, therefore, be governed by pre-MMA rules. That is true of the 2006 settlements here (J.A.34 ¶23; Pet.App.27a n.9), but is decreasingly likely for settlements occurring in 2007 and later. This lag explains the decline in reverse-payment rates after 2006. The MMA's remedial changes just took time to affect ensuing settlements.

Declining 2006-2011 rates are particularly significant because that period coincides with the

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[1] Overview of Final Settlements

(2004-2011)

Fiscal Year	2004	2005	2006	2007	2008	2009	2010	2011
Final Settlements	14	11	28	33	66	68	113	156
Potential Pay-for-Delay	0	3	14	14	16	19	31	28
	0%	27%	50%	42%	24%	28%	27%	18%

From presentation by Bradley S. Albert, Deputy Assistant Director, FTC, *"Are Reverse Payments Dead?"* program sponsored by ABA Section of Antitrust Law, Healthcare and Pharmaceuticals Committee (Nov. 10, 2011).

scope-of-the-patent test being the unanimous rule among the circuits that had adjudicated antitrust challenges to final Hatch-Waxman settlements (CA11, CA2, CAFC). During this natural experiment, reverse-payment rates continued falling despite favorable case law.[2]

Beyond the decline in reverse-payment rates post-MMA, the government has not challenged *any* alleged reverse-payment settlement governed by post-MMA law. See *Overview of FTC Antitrust Actions in Pharmaceutical Services and Products* 13-19 (Sept. 2012).

The government has litigated only three reverse-payment cases, including this one, each involving settlements occurring in a discrete era (1997-2006), and all governed by pre-MMA law. See Par/Paddock-B.I.O.20-21 (detailing cases, including FTC's *Provigil* case that *survived* dismissal under the scope-of-the-patent approach).

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[2] Two business days before filing its brief, the FTC issued its FY2012 report, which indicates that of 140 "final settlements," 40 were "potential pay-for-delay." *FY2012 Overview*, *supra*. That would constitute a 28.6% rate, but the FTC reports: "In nearly half of these potential pay-for-delay agreements (19 out of 40 such agreements), compensation took the form of a brand manufacturer's promise not to market an authorized generic ('AG') in competition with the generic manufacturer's product for some period of time ***." *Ibid.* A recent decision applying the Third Circuit's *K-Dur* rule held that such settlements involving a brand-name's agreement not to launch an authorized-generic are *not* "pay-for-delay." *In re Lamictal Direct Purchaser Antitrust Litig.*, No.2:12-cv-00995-WHW-CLW, 2012 WL 6725580, at *6 (D.N.J. Dec. 6, 2012). If that ruling is correct, the "potential pay-for-delay" rate in FY2012 was only 15%.

As the United States twice predicted, the MMA Amendments have reduced incentives for reverse-payment settlements.

D. Pending Legislation to Change the Antitrust Standard for Reverse-Payment Settlements.

Pending legislation would change the antitrust standard for Hatch-Waxman settlements in FTC suits under the FTC Act (*i.e.*, not private cases):

> (2) **Presumption.**—
>
> (A) In General.— *** [A]n agreement shall be presumed to have anticompetitive effects and be unlawful if—
>
> (i) an ANDA filer receives anything of value; and
>
> (ii) the ANDA filer agrees to limit or forego [sic] research, development, manufacturing, marketing, or sales of the ANDA product for any period of time.

S.214, 113th Cong. §3(2) (introduced Feb. 4, 2013), Par/Paddock-Br.App.5a.

Similar bills proposing to change the antitrust standard for FTC actions challenging Hatch-Waxman settlements have stalled in each Congress since 2006. See Solvay-Cert.Br.19 n.7 (listing unenacted bills).

E. The Solvay and Par/Paddock Settlement

Solvay sued Watson and Paddock, separately, for patent-infringement in 2003. The cases proceeded in the Northern District of Georgia until 2006, when Solvay settled separately with Watson and Par/Paddock. The court encouraged respondents to

settle. J.A.97-98 ("[Solvay and Par/Paddock] consented to judgment through a final settlement, which was encouraged by the Court pursuant to its Local Rules ***."); J.A.95 ("This has all the appearances of a long, complicated, expensive, difficult case. Is there anything that I can do to prevent any of that from happening?").

Claim-construction briefs and *partial* summary judgment motions remained pending at settlement, and the court never made any substantive rulings. J.A.55 ¶90.

Respondents settled under Eleventh Circuit precedent holding that final settlements of non-sham Hatch-Waxman litigation that do not restrict generic competition beyond the patent's exclusionary grant do *not* violate the antitrust laws, regardless of reverse-payments. *Andrx Pharms.* v. *Elan*, 421 F.3d 1227, 1235 (CA11 2005); *Schering-Plough*, 402 F.3d at 1065-1066; *Valley Drug*, 344 F.3d at 1308.

The FTC investigated the settlements for two years (taking twenty-one depositions). The district court dismissed the FTC's ensuing complaint, relying on the same Eleventh Circuit precedents under which respondents settled. *In re AndroGel Antitrust Litig.*, 687 F.Supp.2d 1371 (N.D.Ga. 2010), Pet.App.37a-61a. The Eleventh Circuit affirmed under the same precedents. Pet.App.1a-36a.

Follow-on private cases survived dismissal because the private plaintiffs alleged sham-litigation. The district court ultimately granted summary judgment against the private plaintiffs, holding that neither the patent litigations nor the settlements were shams. *In re AndroGel Antitrust Litig.*, No.

1:09-MD-2084-TWT, 2012 WL 5352986, at *7-18 (N.D.Ga. Oct. 30, 2012).

***

The following is undisputed:

1. *This is a pre-MMA case and, therefore, is not governed by current Hatch-Waxman law.*

This case involves ANDAs filed before the MMA became effective. J.A.34 ¶23. Consequently, except for the requirement that the settlements and related agreements were filed with the DOJ/FTC, the MMA's remedial changes do not apply.

2. *Paddock copied AndroGel® unaware of any patent because under the old Patent Act, Solvay's patent application was not public.*

The FDA approved Solvay's New Drug Application (NDA) for AndroGel® in February 2000, and Solvay began sales *without* patent protection. J.A.37-38 ¶¶33-34, 39. Solvay's sales nonetheless were exclusive for three years under FDA regulation—an important fact because it explains (to us now and to the generic industry then) why AndroGel® had exclusive, growing sales without patent protection. J.A.37 ¶34; Pet.App.39a.

Solvay applied for a patent in August 2000. J.A.38 ¶39. But that application was confidential under then-existing law; Congress amended the Patent Act three months later to make future applications public. 35 U.S.C. 122(b)(1)(A) (effective Nov. 29, 2000) ("[E]ach application for a patent shall be published ***.").

AndroGel®'s growing sales and apparent lack of patent protection, along with the publicly discernible sunset on its three-year exclusivity, attracted generic attention. In December 2000, more than two years before Solvay's regulatory exclusivity would expire in February 2003, Paddock undertook to copy AndroGel® "as close as humanly possible," intending to file a *Paragraph-I* ANDA (which applies when there is *no patent*), as opposed to a Paragraph-IV. *AndroGel*, 2012 WL 5352986, at *3.

Paddock's world changed in January 2003 when, one-month before the three-year exclusivity would expire, Solvay's patent issued. J.A.39 ¶42; *AndroGel*, 2012 WL 5352986, at *3 n.4 ("The Generics did not realize that AndroGel® was patent protected because Solvay's patent application was not public."). Paddock stopped its bioequivalence work, later resuming with the fallback hope of becoming the first Paragraph-IV filer. See *AndroGel*, 2012 WL 5352986, at *3.

Paddock filed its Paragraph-IV in May 2003, unaware that Watson had filed days earlier. *Ibid.*; Pet.App.41a; J.A.39-40 ¶¶44-45. Paddock never had been involved in a Paragraph-IV case and had *not* anticipated one, so it partnered with Par to manage the inevitable litigation in exchange for a share of potential generic profits. Pet.App.41a; J.A.40, 47 ¶¶46, 69.

When Solvay subsequently sued Watson and Paddock in August 2003, the ANDA-filing numbers in the complaints were the first public indication that there were two Paragraph-IV filers and that Watson was first-filer. J.A.40 ¶47; *ANDA Litigation*, *supra*,

at 138 ("A key driver for nonlitigation alternatives is whether the generic party is a Paragraph IV first-filer, and this may not be known until around the time of the initial pleadings.").

3. *Par/Paddock could not have obtained an earlier settlement-entry date even absent any alleged reverse-payment.*

Throughout the litigations, Par/Paddock were blocked by Watson's first-filer exclusivity. J.A.40 ¶45. When the Hatch-Waxman thirty-month stay expired in January 2006, Watson, as first-filer, received final FDA approval and was free to launch its product, but FDA regulation barred Par/Paddock from marketing until 180-days after Watson. J.A.28, 33-34, 41-42 ¶¶2, 22-23, 52-54. Because Watson never launched, Par/Paddock never could. *Ibid.*

After three-years of litigation, Solvay reached settlement terms with Watson, permitting Watson to enter no later than August 2015 (five years *before* patent expiration). J.A.44-47 ¶¶60-67. After concluding its settlement terms with Watson, Solvay separately offered Par/Paddock the same entry terms subject to Watson's exclusivity. J.A.47 ¶71. Because that was the earliest settlement-entry date possible for a second-filer, Par/Paddock "quickly accepted." *Ibid.* Solvay's internal negotiation documents indicate a counter-offer by Watson, J.A.115-vol.2, but none by Par/Paddock, who were an entry-date taker, not maker.

When Par/Paddock settled with Solvay, Watson's 180-day exclusivity still applied. J.A.40 ¶45. Thus, Par/Paddock could obtain the same entry date as Watson "only if Watson did not assert its 180-day

generic exclusivity period." Pet.App.44a. After the parties executed separate, confidential settlement agreements, Watson later relinquished its first-filer exclusivity with the FDA, furnishing Par/Paddock an unanticipated windfall: the same entry date as the first-filer. J.A.100.

4. *The FTC does not allege that Par/Paddock were aware that Solvay planned to introduce a new AndroGel® version in 2015.*

The FTC alleges that the 2015 settlement-entry date had little value:

> *Watson* agreed not to market generic AndroGel until 2015 even though it knew of Solvay's plans to introduce a "line extension" product that would eliminate or substantially reduce potential sales of generic AndroGel by 2015. *** *Solvay told Watson* of its plans for a line extension product during settlement negotiations.

J.A.45 ¶¶62-63 (emphasis added); see FTC-Br.11.

Conspicuously absent from these allegations is any mention of Par/Paddock, who were in the pre-MMA backseat throughout.

5. *Respondents settled under Eleventh Circuit precedent.*

The scope-of-the-patent test governed respondents' settlements, which undisputedly qualify for its safe-harbor. After two-years of investigation and compulsory process, the FTC does *not* allege that either settlement entails restrictions beyond the patent's exclusionary grant, Solvay's patent was obtained by fraud, or the patent-litigations were shams. J.A.46, 49, 53 ¶¶65, 76, 86.

Contemporaneous with the settlements, Solvay and Watson, and Solvay and Par, entered into separate co-marketing agreements for AndroGel®. J.A.46, 49-50 ¶¶66, 77. No legal objection to the co-marketing agreements exists beyond the FTC's objection to the simultaneity with settlement. See *Sorrell* v. *IMS Health*, 131 S.Ct. 2653, 2659 (2011) ("Speech in aid of pharmaceutical marketing *** is a form of expression protected by the Free Speech Clause of the First Amendment.").

Solvay and Paddock entered a manufacturing agreement, without which Solvay's sole source for AndroGel® was a company in Europe. J.A.36-37, 52-53 ¶¶32, 84.

6. *The District Court's Consent Judgment and Order of Permanent Injunction binds Solvay and Par/Paddock and restrains Par/Paddock's generic entry until 2015.*

Solvay and Par/Paddock ended their litigation by petitioning the court to enter a consent judgment. J.A.47, 50 ¶¶68, 80. The resulting Consent Judgment and Order of Permanent Injunction (J.A.97-102) is a final judgment with *res judicata* effect that restrains Par/Paddock's generic entry, binding Solvay and Par/Paddock to their compromise entry terms.

7. *After the Eleventh Circuit affirmed dismissal, the Third Circuit decided* K-Dur.

"The key allegation in the FTC's complaint is that [Solvay] was 'not likely to prevail' in the infringement actions that it brought against the generic manufacturers and then settled." Pet.App.3a; see J.A.53 ¶86. The Eleventh Circuit held that this

allegation did not state an antitrust claim against settlements within the scope-of-the-patent. Pet.App.28a-30a. That decision followed Eleventh Circuit precedent and accorded with the circuits that had adjudicated antitrust challenges to final Hatch-Waxman settlements. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (CAFC 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (CA2 2005).

Three months later, the Third Circuit became the only circuit to reject the scope-of-the-patent approach in favor of a presumption that "treat[s] any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade." *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (CA3 2012).

In rejecting three circuits' decisions, the Third Circuit purported that its "practical analysis is supported by a long line of Supreme Court cases recognizing that valid patents are a limited exception to a general rule of the free exploitation of ideas." *Id.* at 215. But the only Supreme Court case the Third Circuit discusses is *Edward Katzinger Co.* v. *Chicago Metallic*, 329 U.S. 394 (1947), abrogated by *Lear* v. *Adkins*, 395 U.S. 653 (1969), overruling in part *Automatic Radio* v. *Hazeltine Research*, 339 U.S. 827 (1950).

The Third Circuit overlooked that *Lear* abrogated *Katzinger*, which relied on the now-overruled patent-licensee-estoppel rule. See Par/Paddock-B.I.O.33-40. Neither any other court adjudicating antitrust

challenges to Hatch-Waxman settlements nor the FTC cites *Katzinger*.

ARGUMENT

I. For Patent-Based Restraints Of Trade, The Rule Of Reason Begins With The Scope Of The Patent.

A. First Principles

Statutory patent monopolies authorize restraints of trade and exclusionary conduct that would violate our antitrust laws absent patent protection. The Constitution provides: "Congress shall have Power *** To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries ***." U.S.Const.art.I, §8, cl.8. As this Court observed:

> This subject was among the first which followed the organization of our government. It was taken up by the first congress at its second session, and an act was passed authorising a patent to be issued to the inventor of any useful art, etc. on his petition, 'granting to such petitioner, his heirs, administrators or assigns, for any term not exceeding fourteen years, the sole and exclusive right and liberty of making, using, and vending to others to be used, the said invention or discovery.'

Grant v. *Raymond*, 31 U.S. 218, 241 (1832) (Marshall, C.J.) (quoting Act of Apr. 10, 1790, ch.7, §1).

Our founders thus viewed patent rights as essential for the innovation that would power our nation's free-market economy. *Id.* at 241 ("To promote the progress of useful arts, is in the interest

and policy of every enlightened government[,] [and] entered into the views of the framers of our constitution ***.").

"The law has thus impressed upon [a patent] all the qualities and characteristics of property, for the specified period; and has enabled [a patentee] to hold and deal with it the same as in case of any other description of property belonging to him ***." *Wilson* v. *Rousseau*, 45 U.S. 646, 674 (1846); see *Festo* v. *Shoketsu Co.*, 535 U.S. 722, 730 (2002) ("The [patent] monopoly is a property right ***."); *DOJ/FTC Guidelines* §1.0 (recognizing that patent laws "establish[] enforceable property rights for the creators of new and useful products").

The most basic right of any patentee is the right to exclude others from using her property. 35 U.S.C. 154(a)(1) ("Every patent shall contain *** a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention ***."); *Microsoft* v. *i4i*, 131 S.Ct. at 2242 ("[A] patent grants certain exclusive rights to its holder, including the exclusive right to use the invention during the patent's duration."); *Dawson Chem.* v. *Rohm & Haas*, 448 U.S. 176, 215 (1980) ("[T]he essence of a patent grant is the right to exclude others from profiting by the patented invention.").

Our law recognizes that to enjoy fully her property right and maximize her return during the patent term, a patentee may enter all manner of licenses:

> The very object of [the patent] laws is monopoly, and the rule is, with few exceptions, that any

> conditions which are not in their very nature illegal with regard to this kind of property, imposed by the patentee and agreed to by the licensee for the right to manufacture or use or sell the article, will be upheld by the courts.

Bement v. *Nat'l Harrow*, 186 U.S. 70, 91 (1902).

Our nation early-on made the *policy choice* to accept exclusion in the short-run for sake of promoting innovation and competition in the long-run, and, thereby, achieve hoped-for *net* gains for consumer welfare. *E.g.*, *Scott Paper* v. *Marcalus Mfg.*, 326 U.S. 249, 255 (1945) ("The aim of the patent laws is not only that members of the public shall be free to manufacture the product or employ the process disclosed by the expired patent, but also that the consuming public at large shall receive the benefits of the unrestricted exploitation, by others, of its disclosures."); *DOJ/FTC Guidelines* §1.0 (observing patent law's "purpose of promoting innovation and enhancing consumer welfare"); Frank H. Easterbrook, *Ignorance and Antitrust*, in *Antitrust, Innovation, and Competitiveness* 119, 122-123 (Thomas Jorde & David Teece eds., 1992) ("An antitrust policy that reduced prices by 5 percent today at the expense of reducing by 1 percent the annual rate at which innovation lowers the costs of production would be a calamity. In the long run a continuous rate of change, compounded, swamps static losses.").

Exclusion is short-lived, while the public-benefit is enduring: "A suppression can endure but for the life of the patent, and the disclosure he has made will enable all to enjoy the fruit of his genius." *Heaton-*

Peninsular v. *Eureka Specialty*, 77 F. 288, 294-295 (CA6 1896), quoted in *Bement*, 186 U.S. at 90.

For these reasons, patentees can enter into restraints of trade and engage in exclusionary conduct that would violate the antitrust laws absent patent protection: "The patent laws which give a 17-year monopoly on 'making, using, or selling the invention' are *in pari materia* with the antitrust laws and modify them *pro tanto*." *Simpson* v. *Union Oil*, 377 U.S. 13, 24 (1964).

Examples of restraints of trade or exclusionary conduct that do *not* violate the antitrust laws because they are within the scope-of-the-patent include: (i) territorial market-allocation; (ii) field-of-use restrictions and customer-allocation; (iii) output-limitation; and (iv) refusals-to-deal.

(i) Territorial market-allocation. Statute authorizes patentees to allocate markets with or among licensees: "The applicant, patentee, or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States." 35 U.S.C. 261; *e.g.*, *Dunlop* v. *Kelsey-Hayes*, 484 F.2d 407, 417 (CA6 1973) (holding licenses with exclusive territories "cannot be characterized as true horizontal agreements dividing markets" but are "merely territorial licenses granted by a patentee such as are permitted by 35 U.S.C. § 261"), cited in U.S.Br.6, *Andrx*, *supra* ("[A] patent license with territorial restrictions [was] held not to offend the antitrust laws in *Dunlop*."); *Brownell* v. *Ketcham Wire*, 211 F.2d 121, 128-129 (CA9 1954) ("It is a fundamental

rule of patent law that the owner of a patent may license another and prescribe territorial limitations. *** Exclusive territorial licenses granted under patents are old in the law."); 6 Donald S. Chisum, *On Patents: A Treatise on the Law of Patentability, Validity, and Infringement* §19.04[3][h] (2005) ("[A] patent owner may assign or license the right to practice the invention on a territorially restricted basis.").

Thus, in the "paradigmatic" example of *per se* unlawful market-allocation discussed in FTC-Br.19-24, *Palmer* v. *BRG of Georgia*, the market-allocation agreement would have been upheld if it had been a patent license.

Palmer involved an agreement between Harcourt Brace Javanovich (HBJ), the nation's largest bar-review course provider, and BRG, a course provider in Georgia. 498 U.S. at 46-47. The two competed in Georgia until HBJ granted BRG an exclusive-license to use the "Bar/Bri" trade-name there. *Ibid.* They agreed that BRG would operate inside Georgia, and HBJ elsewhere. *Ibid.* *Palmer* held the agreement unlawful *per se* because "[e]ach agreed not to compete in the other's territories[,] [and] [s]uch agreements are anticompetitive regardless of whether the parties split a market within which both do business or whether they merely reserve one market for one and another for the other." *Id.* at 49-50.

If *Palmer* had involved a legitimate dispute between HBJ's *patented* product and BRG's alleged-infringing product, to resolve the dispute and *induce* BRG to cease infringing, HBJ could have granted BRG an exclusive-license in Georgia (*i.e.*, exclusive

even as to HBJ) while HBJ practiced the patent elsewhere. See 35 U.S.C. 261; *Brownell*, 211 F.2d at 128-129 (upholding against antitrust claims an exclusive-license for U.S. sales, reserving to the patentee ex-U.S. sales); *Becton, Dickinson* v. *Eisele*, 86 F.2d 267, 271 (CA6 1936) (holding that territorial market-allocation is "within the scope of patent monopoly *** and so does not offend against the anti-trust laws"); 2 Herbert Hovenkamp et al., *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* §33.3 (2012) (explaining that §261 "authorizes the patentee to give one licensee an exclusive right to practice the patent in one territory, a second licensee to practice in a second territory, and so on").

Patent-infringement suits commonly settle through such rent-sharing licenses. See 1 Hovenkamp, *supra*, §7.1a. Statutory patent monopolies authorize patentees and *patentless* infringers to enter licenses that would constitute illegal "treaties with competitors" absent the patent. FTC-Br.23 (alteration omitted).

(The trade-name license in *Palmer* could not achieve this result because trade-names do not entail the monopolies granted to patents. *DOJ/FTC Guidelines* §1.0 n.1 (explaining that "innovation-related issues that typically arise with respect to patents" are different than the "product-differentiation issues that typically arise with respect to trademarks").)

(ii) ***Field-of-use restrictions and customer-allocation.*** Patentees can enter field-of-use restrictions with licensees, including allocating

classes of customers. *E.g.*, *Gen. Talking Pictures* v. *Western Electric*, 305 U.S. 124, 125-127 (1938) (upholding license restricting sales to residential users, not commercial users, as "reasonably within the reward which the patentee by grant of the patent is entitled to secure"); 6 Chisum, *supra*, §19.04[3][i] ("[T]he Supreme Court held that use-restricted licenses were not illegal and violation of such restrictions could be enforced through suit for infringement.").

(iii) Output-limitation. Patentees and licensees generally may enter output-limitation restraints. *E.g.*, *North Drive-In Theatre* v. *Park-In Theatres*, 248 F.2d 232, 236 (CA10 1957) (holding patentee acted within patent scope by limiting licensee to constructing only one of the patented product); *Aspinwall Mfg.* v. *Gill*, 32 F. 697, 698 (C.C.N.J. 1887) ("[D]efendants cannot pretend that their license to build 100 machines gave them any right to build any more than that; and it is clear, therefore, that in making the remaining 25 machines they were acting without authority."); 2 Hovenkamp, *supra*, §32.1 ("[C]ourts have generally been tolerant of horizontal output limitations in intellectual property licenses, at least when the restriction was imposed by the licensor in each license individually and there was no proof of an output limitation agreement among the licensees themselves.").

(iv) Refusals-to-deal. Patentees have broader refusal-to-deal rights than antitrust monopolists. *E.g.*, *In re Independent Service Organizations Antitrust Litigation*, 203 F.3d 1322, 1324-1327 (CAFC 2000) (upholding Xerox's refusal to sell patented parts to independent service organizations

that competed with Xerox in servicing its copiers, concluding that Xerox's "intent in refusing to deal and any other alleged exclusionary acts *** are irrelevant to antitrust law," because "the right of the patentee to refuse to sell or license in markets within the scope of the statutory patent grant" is settled), cited in U.S.Br.8, *Andrx*, *supra* ("[P]atent holders can lawfully refuse to license competitors to produce the patented article ***."); 6 Chisum, *supra*, §19.04[3][f] ("Generally, the patent owner has discretion whether and to whom he will issue a license.").

But a non-patentee monopolist may under certain circumstances violate the antitrust laws by refusing to deal. *Aspen Skiing* v. *Aspen Highlands*, 472 U.S. 585, 610-611 (1985) (holding that ski company's refusal to participate in joint-lift ticket program with smaller competitors violated the antitrust laws).

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It is settled law that to reap the full reward of their time-limited monopolies, patentees may enter into agreements that restrain the practice of the patent (or engage in exclusionary unilateral conduct) for the patent-holder's financial benefit, including by entering into mutually beneficial agreements with alleged infringers.

The equally settled test to determine whether a patentee has entered into a restraint (or engaged in conduct) outside the protection of the temporary monopoly and, therefore, potentially in violation of the antitrust laws, begins by inquiring whether the restraint or conduct exceeds the scope-of-the-patent. *E.g.*, *Line Material*, 333 U.S. at 353 ("If the limitations in a license reach beyond the scope of the

statutory patent rights, then they must be tested by the terms of the Sherman Act."); *Gen. Talking Pictures*, 305 U.S. at 127 ("[T]he patentee may grant a license upon any condition the performance of which is reasonably within the reward which the patentee by the grant of the patent is entitled to secure."); *Cipro*, 544 F.3d at 1336 (CAFC 2008) ("[T]he outcome is the same whether the court begins its analysis under antitrust law by applying a rule of reason approach to evaluate the anti-competitive effects, or under patent law by analyzing the right to exclude afforded by the patent.").

B. This Court never has upheld an antitrust claim against patent enforcement or licensing within the scope of a non-sham patent.

1. *Standard Oil*

Standard Oil resolves the key questions here, teaching that: (i) parties may settle patent-litigation without antitrust liability as long as there were "legitimately conflicting claims," 283 U.S. at 171; (ii) such conflict turns on the nominal scope-of-the-patent, which is *not* second-guessed by inquiring whether infringement would have been proven, *id.* at 181; and (iii) the financial terms and consideration of a settlement are irrelevant, *id.* at 171-172.

All the circuits that have ruled on final Hatch-Waxman settlements, except the Third Circuit, have relied on *Standard Oil*. See *Schering-Plough*, 402 F.3d at 1072 ("That the parties to a patent dispute may exchange consideration to settle their litigation has been endorsed by the Supreme Court."); *Cipro*, 544 F.3d at 1333; *Tamoxifen*, 466 F.3d at 202. The FTC's concession that *Standard Oil* establishes the

general rule that patent-settlements do not violate the antitrust laws, FTC-Br.26-27, makes the Third Circuit's failure to cite it particularly telling.

In *Standard Oil*, the government sought to enjoin, under Sherman Act §§1-2, agreements among four "primary defendants" concerning competing patents on "cracking" processes for extracting gasoline from crude-oil residue. Standard first patented the process, earning royalties for seven years by licensing it to fifteen companies. 283 U.S. at 167.

Because "cracking was not controlled by any fundamental patent," three companies subsequently patented competing processes. *Ibid.* Patent litigation ensued. To settle and avoid further litigation, the companies cross-licensed the patents, enabling each to use the previously competing processes and to license them to third-parties for royalties shared among the defendants. *Id.* at 168.

The government alleged that the settlement and licenses constituted unlawful restraints on cracking-supplied gasoline: "Control is alleged to be exerted by means of seventy-nine contracts concerning patents relating to the cracking art." *Id.* at 165-166.

The Court unanimously held, in an opinion by Justice Brandeis, that neither the settlement nor the patent-licensing and royalty arrangements violated the Sherman Act. Because the patents were presumptively valid, with no allegation of bad-faith acquisition, the Court did "not consider any of the issues concerning the validity or scope of the cracking patents." *Id.* at 181. The Court's methodical analysis (numbered as below) is instructive.

First, the Court rejected defendants' contention that patent-settlements and -licenses are exempt from antitrust scrutiny: "Such contracts must be scrutinized to ascertain *whether the restraints imposed* are regulations reasonable under the circumstances, or whether their effect is to suppress or unduly restrict competition." *Id.* at 169 (emphasis added). The Court emphasized special concerns with combinations among *multiple* patent-holders:

> And pooling arrangements may obviously result in restricting competition. *** Hence the necessary effect of patent interchange agreements, and the operations under them, must be carefully examined in order to determine whether violations of the Act result.

Id. at 169-170.

Second, the Court rejected the government's contention that dividing royalties (*i.e.*, monopoly rents) through settlement and cross-licenses among formerly competing patent-holders necessarily violated the Sherman Act: "Where there are legitimately conflicting claims or threatened interferences, a settlement by agreement, rather than litigation, is not precluded by the Act." *Id.* at 171 (citing *Virtue* v. *Creamery Package*, 227 U.S. 8, 33 (1913)).[3]

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[3] *Virtue* v. *Creamery* rejected a private antitrust claim alleging that competing patent-holders had settled patent-litigation with a license-and-royalty agreement that eliminated competition between them and restrained third-parties' manufacturing of certain dairy equipment. The Court held: "[P]atents are not so used [in violation of law] when the rights conferred upon them

Standard Oil observed, moreover, the frequent necessity of exchanging financial consideration in reaching settlements: "An interchange of patent rights and a division of royalties according to the value attributed by the parties to their respective patent claims is frequently necessary if technical advancement is not to be blocked by threatened litigation." *Ibid.* Thus, the Court wholly rejected the government's attempt to interject the parties' financial consideration into the antitrust analysis.

Third, the Court rejected the government's contention that royalties imposed through the settlement and cross-licenses were so onerous as to exclude potential competitors from using the cracking processes and, thereby, unreasonably restrained gasoline supply: "This argument ignores the privileges incident to ownership of patents." *Id.* at 172.

Fourth, because patent-pooling to sustain industry royalty rates would exceed patent scope, the Court agreed that the government's "main contention" required an evidentiary assessment:

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by law are only exercised." 227 U.S. at 33 (McKenna, J.). The Court observed that the agreement "was but a settlement of claims growing out of reciprocal charges of infringement." *Ibid.* The Court also rejected the claim that because the patent-holders ultimately were unsuccessful in asserting one of the patents, the settlement violated the antitrust laws: "[T]his is not an action for malicious prosecution. It is an action under the Sherman Anti-trust Act for the violation of the provisions of that act, seeking treble damages." *Id.* at 38. In other words, the adjudicated scope-of-the-patent was irrelevant.

> [A] pooling of competing process patents, or an exchange of licenses for the purpose of curtailing the manufacture and supply of an *unpatented* product, is beyond the privileges conferred by the patents and constitutes a violation of the Sherman Act. The lawful individual monopolies granted by the patent statutes cannot be unitedly exercised to restrain competition.

Id. at 174 (citing *Standard Sanitary* v. *United States*, 226 U.S. 20 (1912)) (emphasis added).[4]

Fifth, the Court assessed the evidence and held that none indicated that defendants acted beyond their patent grants: "To warrant an injunction which would invalidate the contracts here in question, *and require either new arrangements or settlement of the conflicting claims by litigation*, there must be a definite factual showing of illegality." *Id.* at 179 (citing *Chicago Board of Trade* v. *United States*, 246 U.S. 231, 238 (1918)) (emphasis added).[5]

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[4] Justice McKenna's opinion for the Court in *Standard Sanitary*, invalidating unlawful patent-pooling only one year before his opinion for the Court upholding legitimate patent-licenses in *Virtue* v. *Creamery*, see p.41 n.3, *supra*, underscores the difference between the two types of restraints. *Standard Sanitary* upheld the government's antitrust claim against multiple companies that consolidated their competing patents on the manufacture of enameled-ironware (*e.g.*, bathtubs) in one party. That party then set prices for 85% of manufacturers and re-sale prices for distributors. 226 U.S. at 47-49.

[5] *Chicago Board of Trade* rejected the government's claim that the commodity exchange's "call" rule, which prohibited trading grains afterhours at prices other than those bid at the close of trading, necessarily violated the Sherman Act. The Court

Sixth, disposing of the case, the Court rejected the government's attempt to base its antitrust claim on the judicially tested strength *vel non* of the patents. The government contended that the "patents were either invalid or narrow in scope; [and] that there was no substantial foundation for the alleged conflicts and threatened infringement suits[.]" *Id.* at 180. The Court rejected these contentions *despite* the district court having questioned what the adjudicated scope-of-the-patents would have been:

> The District Court stated that the particular claims should be interpreted narrowly, and that the respective inventions might be practised without infringement of adversely owned patents. *But it confirmed the finding of presumptive validity and did not question the finding of good faith.*

Id. at 181 (emphasis added).

By asking this Court to adopt a rule requiring judicial appraisal of financial consideration underlying settlements of undisputedly good-faith patent litigation, the FTC asks this Court to reject *Standard Oil*.

2. *The Cartel Cases*

The FTC cites five precedents for the proposition that "this Court has never suggested that the bundle of rights a patent provides to its holder includes the right to share the patentee's monopoly profits to induce potential competitors to abandon their efforts

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upheld the practice under the rule of reason. 246 U.S. at 237-239 (Brandeis, J.).

to compete or stay out of the market altogether." FTC-Br.29. But none of the cases involve a single patentee granting a license to a *patentless* infringer to settle litigation.

Instead, each case—following *Standard Oil*'s admonition that patents "cannot be unitedly exercised to restrain competition," 283 U.S. at 174—held that patent-holders exceeded their patent scopes by entering into numerous combinations concerning numerous patents in attempts to cartelize an industry:

- *United States* v. *Singer*, 374 U.S. 174, 197 (1963) ("By aggregating patents in one control, the holder of the patents cannot escape the prohibitions of the Sherman Act. That Act imposes strict limitations on the concerted activities in which patent owners may lawfully engage, and those limitations have been exceeded in this case.");
- *United States* v. *New Wrinkle*, 342 U.S. 371, 380 (1952) ("An arrangement was made between patent holders to pool their patents and fix prices on the products for themselves and their licensees. The purpose and result plainly violate the Sherman Act.");
- *United States* v. *U.S. Gypsum*, 333 U.S. 364, 400-401 (1948) (holding that owner of multiple patents entering into industry-wide licenses requiring royalties on both patented *and unpatented* products exceeded the scope-of-the-patents: "[A patentee] acting in concert with all members of an industry, to issue substantially identical licenses to all members of the industry under the terms of which the industry is completely regimented, the

production of competitive unpatented products suppressed, a class of distributors squeezed out, and prices on unpatented products stabilized [violates the antitrust laws].");

- *United States* v. *Line Material*, 333 U.S. 287, 314 (1948) ("[W]hen *patentees* join in an agreement as here to maintain prices on their several products, that agreement *** is unlawful *per se* under the Sherman Act.") (emphasis added);
- *United States* v. *Masonite*, 316 U.S. 265, 280 (1942) (holding patent-pooling and price-fixing conspiracy exceeded patent scope: "[T]he price regulation was based on mutual agreement among distributors of competing products, some of whom had competing patents, as we have noted. None of these patents *** had been held to conflict with or infringe the Masonite patents.").

The out-of-bounds restraints in each case rather than the financial consideration underlying the agreements controlled the outcome. *Singer*, *New Wrinkle*, *Gypsum*, *Line Material*, and *Masonite* confirm this Court's long-adherence to the scope-of-the-patent approach in evaluating patent-based restraints of trade. The FTC's reliance on these cases underscores the lack of authority for a different approach.

3. *Walker Process*

Walker Process teaches that, fraud aside, patent-enforcement within the patent's nominal scope is protected from antitrust scrutiny—regardless of any ensuing merits determination. 382 U.S. at 177. For antitrust purposes, within-the-scope patent-enforcement is risk-free. (Non-antitrust, patent-law

consequences for trivial suits exist. *E.g.*, 35 U.S.C. 285.)

Walker Process refutes the FTC's unprecedented, *citeless* contention that patents confer antitrust protection only if patentees accept litigation risk-of-loss. FTC-Br.26. Absent fraud/sham, patentees' antitrust exposure is unrelated to the vicissitudes of patent-litigation, much less any requirement to embrace those risks by forfeiting the right to self-insure through settlement. See *Watson*, Pet.App.32a ("Even the confident patent owner knows that the chances of prevailing in patent litigation rarely exceed seventy percent.").

Walker Process established a fraudulent-procurement exception to the general antitrust exemption for patent-enforcement: "[E]nforcement of a patent procured by fraud on the Patent Office may be violative of §2 of the Sherman Act provided the other elements necessary to a §2 case are present." 382 U.S. at 174. The Court did *not* distinguish a patentee's unilateral enforcement from that of an assignee acting by agreement: "This conclusion applies with equal force to an assignee who maintains and enforces the patent with knowledge of the patent's infirmity." *Id.* at 177 n.5.

The Court rejected the contention that knowingly enforcing a fraudulent patent alone establishes an antitrust claim: "[T]he area of *per se* illegality is carefully limited. We are reluctant to extend it on the bare pleadings and absent examination of market effect and economic consequences." *Id.* at 178.

Walker Process explained that fraudulent procurement may expose a patent-holder to antitrust

liability for exceeding the legitimate scope-of-the-patent:

> The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies *spring from backgrounds free from fraud or other inequitable conduct and that such monopolies* are kept within their legitimate scope.

Precision Instrument v. *Automotive Maintenance Machinery*, 324 U.S. 806, 816 (1945), quoted in *Walker Process*, 382 U.S. at 177 (emphasis supplied to highlight the language elided from the FTC's quotation of *Precision Instrument* at FTC-Br.48).[6]

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[6] The FTC cites *Precision Instrument* for the proposition that antitrust law should look beyond nominal patent scope because of "the public benefit from judicial testing of patent scope and elimination of invalid patents." FTC-Br.48. But *Precision Instrument* has nothing to do with judicial testing of patent scope or validity. Like *Walker Process*, *Precision Instrument* is about fraudulent-procurement. Patent-interference litigation settled only after Precision conceded that its interfering application was fraudulent. 324 U.S. at 810-814. Notwithstanding Automotive's knowledge of the fraud, Automotive agreed through settlement to be assigned Precision's application. *Id.* at 813-814. When Automotive enforced the ensuing patent against Precision, the Court balked: "The guiding doctrine in this case is the equitable maxim that 'he who comes into equity must come with clean hands.'" *Id.* at 814.

The FTC's omission of the words "*spring from backgrounds free from fraud or other inequitable conduct*" from its quotation of *Precision Instrument* is a telling admission of the lack of precedent for the FTC's contention that antitrust analysis requires "judicial testing of patent scope and elimination of invalid patents." FTC-Br.48.

Walker Process's use of "legitimate scope" was thus nominal patent scope—"free from fraud or other inequitable conduct," 382 U.S. at 177—not adjudicated scope as would be determined on the merits in a patent-infringement proceeding.

Justice Harlan elaborated on this important distinction between nominal and adjudicated scope in his oft-cited concurrence:

> [A] private cause of action would *not* be made out if the plaintiff: (1) showed no more than invalidity of the patent arising, for example, from a judicial finding of "obviousness," or from other factors sometimes compendiously referred to as "technical fraud"; ***.
>
> It is well also to recognize the rationale underlying this decision, aimed of course at achieving a suitable accommodation in this area between the differing policies of the patent and antitrust laws. To hold, as we do, that private suits may be instituted under §4 of the Clayton Act to recover damages for Sherman Act monopolization knowingly practiced under the guise of a patent procured by deliberate fraud, cannot well be thought to impinge upon the policy of the patent laws to encourage inventions and their disclosure. Hence, as to this class of improper patent monopolies, antitrust remedies should be allowed room for full play. On the other hand, to hold, as we do *not*, that private antitrust suits might also reach monopolies practiced under *patents that for one reason or another may turn out to be voidable* under one or more of the numerous technicalities attending the issuance of

> a patent, might well chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble-damage suits.

Id. at 179-180 (emphasis added).

Walker Process's antitrust safe-harbor for non-fraudulent enforcement protects against the chilling effect on innovation that would ensue if patentees were subject to antitrust liability simply because they lost a (non-sham) case. Nothing in *Walker Process* suggests that a patentee forfeits that protection by settling the very same non-sham litigation. And, imputing such an exception to the non-sham, scope-of-the-patent safe-harbor would be unsound for two reasons.

First, given that the FTC rejects antitrust assessment of patent merits beyond fraud/sham standards as "doctrinally anomalous and likely unworkable in practice," FTC-Br.53, in a non-sham case there is no principled distinction between the exclusion resulting from litigation versus the exclusion resulting from settlement as long as each is within the scope-of-the-patent. See *PRE*, 944 F.2d 1525, 1528 (CA9 1991) ("A decision to accept or reject an offer of settlement is conduct incidental to the prosecution of the suit and not a separate and distinct activity which might form the basis for antitrust liability."), aff'd, 508 U.S. 49 (1993); *Valley Drug*, 344 F.3d at 1309 ("[L]itigation is a much more costly mechanism to achieve exclusion, both to the parties and to the public, than is settlement.").

Without such a principled distinction, the FTC's rule would merely enact a policy preference for

litigation-to-the-end over settlement. Compare *Microsoft* v. *i4i*, 131 S.Ct. at 2252 ("We find ourselves in no position to judge the comparative force of these policy arguments.").

Second, it would be anomalous if the antitrust rule for patent-settlements were stricter than the rule for pre-suit licenses. Patentees routinely reach mutually beneficial compromises of their patent rights with would-be infringers in pre-suit licenses that entail all manner of bargained-for consideration. See pp.32-33, 34-37, *supra*. The FTC neither (i) explains why a different rule should apply post-suit nor (ii) proffers any limiting-principle to cabin the presumption from spilling into heightened antitrust scrutiny of pre-suit licensing (including treble-damages claims).

4. *Professional Real Estate Investors (PRE)*

PRE teaches that: (i) to pierce *Noerr-Pennington*'s general antitrust immunity for litigation conduct, the suit must be objectively baseless, and the litigant must have an improper subjective motivation; (ii) "objective baselessness" is a threshold inquiry that must be satisfied *before* subjective motivation becomes relevant; (iii) objective baselessness is determined by the nominal (not adjudicated) claim; and (iv) basing antitrust liability solely on parties'

subjective-litigation views would vitiate *Noerr-Pennington*.[7]

PRE thus precludes using parties' subjective-litigation views as the sole basis for a presumptive antitrust violation. The FTC's theory here is that reverse-payments demonstrate shared subjective recognition that a settlement-without-payment would have resulted in an earlier generic-entry date:

> If a settlement without a reverse payment is ultimately consummated, that dynamic provides good reason to *presume* *** that the period of brand-name monopoly the settlement allows is

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[7] *E. R.R. Presidents Conference* v. *Noerr Motor Freight*, 365 U.S. 127 (1961), unanimously reversed a judgment that railroads violated Sherman Act §§1-2 through deceptive publicity against trucking:

> [T]he railroads' sole purpose in seeking to influence the passage and enforcement of laws was to destroy the truckers as competitors for the long-distance freight business. *** The right of the people to inform their representatives in government of their desires with respect to the passage or enforcement of laws *cannot properly be made to depend upon their intent in doing so*. It is neither unusual nor illegal for people to seek action on laws in the hope that they may bring about an advantage to themselves and a disadvantage to their competitors.

Id. at 138-139 (emphasis added); see *United Mine Workers* v. *Pennington*, 381 U.S. 657, 670 (1965) ("*Noerr* shields from the Sherman Act a concerted effort to influence public officials regardless of intent or purpose.").

California Motor Transport v. *Trucking Unlimited*, 404 U.S. 508 (1972), extended *Noerr-Pennington* immunity to parties jointly seeking anticompetitive outcomes from courts. See p.64, *infra*.

> roughly commensurate with the *perceived strength* and scope of the relevant patent.
>
> By contrast, when a Hatch-Waxman settlement provides for a substantial reverse payment, the *most natural inference* is that the payment has purchased an additional increment of market exclusivity.

FTC-Br.35-36 (emphasis added).

This theory has two problems: it incorrectly presumes that a payment reflects the parties' shared subjective-litigation views; and, in any event, *PRE* bars antitrust liability based solely on parties' subjective-litigation views.

First, because Paragraph IV litigation is a "highly artificial act of infringement," *Eli Lilly*, 496 U.S. at 678, the resulting asymmetry of risks between brand-names and generics renders an exchange of financial consideration an unreliable proxy for the parties' subjective views of the patent case. As the United States explained in a 2006 CVSG, "the resulting gross disparities in the litigants' respective risks may tend to increase the cost of settlement for patentees in the Hatch-Waxman context and make reverse payments more likely, even when the patentee's legal claims are strong." U.S.Br.10, *Schering-Plough*, *supra*.

Second, contravening *PRE*, the FTC's presumption improperly establishes antitrust liability on a "natural inference," FTC-Br.36, to be drawn from parties' supposed subjective-litigation views. See U.S.Br.12, *Schering-Plough*, *supra* ("The FTC's approach, however, appears to place undue weight on the parties' subjective views of the strength of the

claims as reflected in the settlement agreement ***."). Critically, this proposed inference would *replace* plaintiffs' burden of proving that defendants "had a conscious commitment to a common scheme designed to achieve an unlawful objective." *Monsanto* v. *Spray-Rite*, 465 U.S. 752, 758, 764 (1984) (rejecting test that "proof of [distributor] termination following competitor complaints is sufficient to support an inference of concerted action," holding: "There must be evidence that tends to *exclude the possibility* that the manufacturer and nonterminated distributors were acting independently.") (emphasis added).

PRE precludes such a presumptive antitrust violation predicated solely on parties' subjective-litigation views. Columbia sued PRE for copyright-infringement. PRE counter-claimed under Sherman Act §§1-2, alleging "that Columbia's copyright action was a mere sham that cloaked underlying acts of monopolization and conspiracy to restrain trade." 508 U.S. at 52.

Although Columbia lost its IP claim on summary judgment, Columbia won summary judgment against PRE's sham-litigation counterclaim because PRE failed to show that Columbia's IP claim was objectively baseless and, therefore, any factual questions as to Columbia's subjective motivation were irrelevant. *Id.* at 53-54. This Court granted certiorari to resolve divergent standards for establishing a sham-litigation antitrust claim under *Noerr-Pennington*. See *Nobelpharma* v. *Implant Innovations*, 141 F.3d 1059, 1071 (CAFC 1998) ("*PRE* and *Walker Process* provide alternative legal grounds

on which a patentee may be stripped of its immunity from the antitrust laws[.]").

PRE concluded that sham-litigation claims cannot be based solely on a litigant's subjective motivation: "[F]idelity to precedent compels us to reject a purely subjective definition of 'sham.' The sham exception so construed would undermine, if not vitiate, *Noerr*. And despite whatever 'superficial certainty' it might provide, a subjective standard would utterly fail to supply 'real intelligible guidance.'" *PRE*, 508 U.S. at 60 (quoting *Allied Tube* v. *Indian Head*, 486 U.S. 492, 508 n.10 (1988)).

Sham-litigation thus requires: (i) an objectively baseless claim; and (ii) an improper subjective motivation by the claimant:

> We now outline a two-part definition of "sham" litigation. First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under *Noerr*, and an antitrust claim premised on the sham exception must fail.

Ibid.

"Objective baselessness" is a threshold inquiry: "Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation. *** This two-tiered process requires the plaintiff to disprove the challenged lawsuit's *legal* viability before the court will entertain evidence of the suit's *economic* viability." *Id.* at 60-61.

Like *Walker Process*, *PRE* explained that even if both elements of the sham exception are met, the antitrust plaintiff still must prove the elements under Sherman Act §§1-2:

> [E]ven a plaintiff who defeats the defendant's claim to *Noerr* immunity by demonstrating both the objective and the subjective components of a sham *must still prove a substantive antitrust violation*. Proof of a sham merely deprives the defendant of immunity; it does not relieve the plaintiff of the obligation to establish all other elements of his claim.

Id. at 61 (emphasis added).

Critically, *PRE* emphasized that the nominal claim, *not* the adjudicated outcome of that claim, controls the antitrust analysis (unless the claimant won, which ends the inquiry altogether):

> [W]hen the antitrust defendant has lost the underlying litigation, a court must "resist the understandable temptation to engage in *post hoc* reasoning by concluding" that an ultimately unsuccessful "action must have been unreasonable or without foundation." The court must remember that "[e]ven when the law or the facts appear questionable or unfavorable at the outset, a party may have an entirely reasonable ground for bringing suit."

Id. at 60 n.5 (quoting *Christiansburg Garment* v. *EEOC*, 434 U.S. 412, 421-422 (1978)).

Echoing Justice Harlan's warning in *Walker Process* about the chilling effect on innovation that would ensue if antitrust liability turned on the

uncertain, adjudicated outcome of litigation, *PRE* held that antitrust liability based solely on subjective intent would thwart incentives for creativity: "[T]o condition a copyright upon a demonstrated lack of anticompetitive intent would upset the notion of copyright as a 'limited grant' of 'monopoly privileges' intended simultaneously 'to motivate the creative activity of authors' and 'to give the public appropriate access to their work product.'" *Id.* at 64 (quoting *Sony* v. *Universal City Studios*, 464 U.S. 417, 429 (1984)).

PRE explained that if a suit has an objective basis, it is beyond the purview of antitrust plaintiffs—or courts—to second-guess the litigant's economic motivations by questioning, for example, whether the suit was worth the candle:

> PRE could not pierce Columbia's *Noerr* immunity without proof that Columbia's infringement action was objectively baseless or frivolous. Thus, the District Court *had no occasion to inquire* whether Columbia was indifferent to the outcome on the merits of the copyright suit, whether any damages for infringement would be too low to justify Columbia's investment in the suit, or whether Columbia had decided to sue primarily for the benefit of collateral injuries inflicted through the use of legal process. Such matters concern Columbia's *economic motivations* in bringing suit, which were rendered *irrelevant* by the objective legal reasonableness of the litigation.

Id. at 65-66 (using "*Contra*" signal to disapprove *Grip-Pak* v. *Illinois Tool Works*, 694 F.2d 466, 472 (CA7 1982) (Posner, J.)) (emphasis added).

PRE thus rejected *Grip-Pak*'s holding that a suit with some objective basis nonetheless could constitute a sham for antitrust purposes if the litigant's improper subjective motivation were evidenced by, for example, spending more in the litigation than it hoped to gain. *Grip-Pak*, 694 F.2d at 472.

For patent-litigation with an objective basis and ensuing settlements within the nominal scope-of-the-patent, a rule presuming such settlements unlawful solely based on alleged "reverse-payments" would vitiate *PRE*'s holding that parties cannot be subjected to antitrust liability solely predicated on subjective-litigation views. The settling parties' *economic* motivations only become relevant if the *legal* infirmity of the settlement is demonstrated by restraints outside the scope-of-the-patent.

C. Traditional antitrust principles do not regulate parties' consideration or compel firms "to pursue the course that maximizes competition and consumer welfare," FTC-Br.51.

Traditional antitrust principles do not generally regulate financial consideration underlying agreements. See, *e.g.*, *Linkline*, 555 U.S. at 448; *Trinko*, 540 U.S. at 408; *Standard Oil*, 283 U.S. at 171-172. The FTC's presumption would depart from these principles by requiring courts to *appraise* any business transactions entered into contemporaneously with Hatch-Waxman settlements. According to the FTC:

> [A] court would need to consider the totality of the circumstances surrounding the agreement,

> relevant considerations would include [1] whether the payment reflected bona fide fair consideration for the property or services; [2] whether other terms of the side transaction comported with industry standards; [3] the existence of previous dealings between the parties on the subject matter of the side transaction; [4] a history of demonstrated interest in or need for the property or services on the part of the brand-name manufacturer; and [5] the course and content of the manufacturers' negotiations over the agreements.

FTC-Br.37-38.

The FTC inaccurately states that the agreements in this case involve "direct payments of money." FTC-Br.36 n.7 (citing nothing). Rather, the alleged "reverse-payments" here are separate co-promotion and manufacturing agreements entered into contemporaneously with the settlements. When stuck with its allegations, the FTC can only contend: "Those agreements made economic sense only as a mechanism for Solvay to pay its nascent generic competitors to delay competing with it, because the marketing agreements and the back-up manufacturing deal had little value to Solvay." FTC-Br.12 (citing J.A.50-53 ¶¶81-85).

Direct payments to delay generic entry are a thing of the past, and concerned *interim*-settlements for generics not to launch "at risk" during litigation. *E.g.*, *Cardizem*, 332 F.3d at 902 (CA6 2003); *Andrx*, 256 F.3d at 803 (CADC 2001); see U.S.Br.17, *Andrx*, *supra* ("The distinction is important because the calculus of competitive costs and benefits is

substantially different for interim settlements and final settlements."). Certainly post-MMA, the FTC has not reported (much less prosecuted) any direct-payment-for-delay settlements.

At bottom, the FTC's presumption is about courts appraising the "economic sense" of business transactions contemporaneous with settlement. What does not making "economic sense" mean? Does it mean that Solvay lost money in its co-marketing agreements with Watson and Par? If so, the FTC does *not* allege that; it alleges instead that Solvay had cheaper co-marketing alternatives. J.A.51 ¶82; see U.S.Br.15-20, *Trinko* (No.02-682) (filed May 23, 2002) (unsuccessfully advocating for an "economic sense" standard).

Under the FTC's rule, brand-names entering into profitable transactions could be subject to potential antitrust liability merely because *more*-profitable alternatives existed. Would the FTC's rule likewise oblige generics to earn only a "fair" profit on such transactions? See *Trinko*, 540 U.S. at 415 ("No court should impose a duty to deal that it cannot explain or adequately and reasonably supervise. The problem should be deemed irremediable by antitrust law ***.") (citations and internal quotation marks omitted); *Brooke Group* v. *Brown & Williamson Tobacco*, 509 U.S. 209, 223 (1993) (describing above-cost predation as "beyond the practical ability of a judicial tribunal to control").

The rudderless appraisal litigation that the FTC proposes would burden courts and parties alike without necessarily leading to reliable antitrust conclusions. See FTC-Br.37 (describing parties'

"heavy burden" to rebut presumption). In *Schering-Plough*, the FTC failed to convince its ALJ after a 40-day trial that the IP-licenses contemporaneous with settlement were a payment-for-delay (which did not deter the FTC from pursuing the case until denial of certiorari). *In re Schering-Plough*, No.9297, 2002 WL 1488085 (F.T.C. June 27, 2002); see also R. Hewitt Pate, Assistant Attorney General, DOJ Antitrust Division, *Antitrust and Intellectual Property* 12 (Jan. 24, 2003) ("The problem is that we have no way definitively to know which situation applies without evaluating the underlying IP rights, a task that is outside our core expertise as antitrust enforcers.").

The FTC concedes that circumscribing financial consideration will result in fewer settlements, FTC-Br.40, compelling parties to forgo settlements "to pursue the course that maximizes competition and consumer welfare," FTC-Br.51, when "competing considerations suggest that the mere presence of a reverse payment in the Hatch-Waxman context is not sufficient to establish that the settlement is unlawful." U.S.Br.11, *Schering-Plough*, *supra*.

D. Consequences

The contention that affirmance "would likely embolden manufacturers to enter into more such agreements, on more harmful terms," FTC-Br.46, presumes that patent-shortening settlements, like those here enabling generic entry five-years before patent expiration, are "harmful." That contention is undermined by the FTC's concession that predicting the but-for outcome would be "doctrinally anomalous and likely unworkable in practice." FTC-Br.53.

The FTC also *ignores* the MMA's remedial amendments. See pp.14-18, *supra*. In particular, due to exclusivity-forfeiture, first-filer settlements can no longer forestall subsequent generic entry. Due to shared-exclusivity, multiple generics can now line up with challenges qualifying for 180-day exclusivity. These changes incentivize *multiple* challengers, particularly given the FTC's finding that once a drug's sales reach $130 million, generics need only a 4% chance of winning to make challenges worthwhile. See p.15, *supra*.

The MMA Amendments have reduced incentives for reverse-payments (as the United States predicted in CVSGs), resulting in declining rates throughout the years when circuits unanimously applied the scope-of-the-patent approach. See pp.21-22, *supra*. Congress chose to reduce incentives for reverse-payments, rather than to prohibit reverse-payments or enact a "presumption" against them.

Congress's intervention with remedial changes and enactment of an antitrust-specific penalty and an antitrust-savings clause are reason for the Court to adhere to, *not* depart from, the common-law precedents that were the backdrop for Hatch-Waxman and the MMA.

These interventions (and pending legislation proposing an antitrust "presumption" *for FTC actions*) indicate higher likelihood for legislative backstop on the Hatch-Waxman settlement issue than is typical in antitrust cases. Congress can enact policy preferences that are not in judges' antitrust toolkits.

The FTC's contention that the scope-of-the-patent approach is a rule of *per se* lawfulness overlooks the FTC's own pending *Provigil* enforcement action, the *AndroGel* private suits, *K-Dur*, and numerous other challenges to Hatch-Waxman settlements that survived dismissal under the scope-of-the-patent approach. See Par/Paddock-B.I.O.20-21.

Far from toothless, this Court has applied the scope-of-the-patent approach both to uphold and to condemn patent-based restraints of trade.

II. The Complaint Fails To State A Claim Against Par/Paddock Under Any Antitrust Standard.

A. The district court order restraining Par/Paddock's generic entry confers *Noerr-Pennington* immunity.

Respondents' private settlement agreements (between Solvay and Watson on one hand, and Solvay and Par/Paddock on the other) could *not* of their own force end the patent litigations:

Solvay and Watson dismissed their litigation "without prejudice" by filing a stipulation of dismissal "without a court order." Fed.R.Civ.P.41(a)(1)(A)(ii).

Solvay and Par/Paddock successfully petitioned the court to enter the Consent Judgment and Order of Permanent Injunction, which: (i) terminated Solvay and Par/Paddock's litigation "with prejudice"; (ii) enjoins Par/Paddock from selling its generic AndroGel® until 2015 at the latest; (iii) guarantees Par/Paddock's right to practice the patent after that date; and (iv) retains continuing jurisdiction to enforce these terms. J.A.99-101.

The order binds Solvay and Par/Paddock to their generic-entry compromise in ways that a settlement agreement alone cannot. *United States* v. *Swift*, 286 U.S. 106, 115 (1932) ("We reject the argument *** that a decree entered upon consent is to be treated as a contract and not as a judicial act."); *SEC* v. *Randolph*, 736 F.2d 525, 528 (CA9 1984) ("A consent decree offers more security to the parties than a settlement agreement where the only penalty for failure to abide by the agreement is another suit."); see *Schering-Plough*, 402 F.3d at 1072 ("Veritably, the Commission's opinion would leave settlements, including those endorsed and facilitated by a federal court, with little confidence.").

Because Solvay and Par/Paddock successfully *petitioned* the court for an order enforcing their compromise generic-entry terms, they are immune from antitrust liability under *Noerr-Pennington*:

> We conclude that it would be destructive of rights of association and of petition to hold that groups with common interests may not, without violating the antitrust laws, use the channels and procedures of state and federal agencies *and courts* to advocate their causes and points of view respecting *resolution of their business and economic interests* vis-à-vis *their competitors*.

California Motor Transport, 404 U.S. at 510-511 (emphasis added); see *Andrx*, 421 F.3d at 1234 (CA11 2005) ("[A]s the Supreme Court has noted, engaging in litigation to seek an anticompetitive outcome from a court is First Amendment activity that is immune from antitrust liability."); *PRE*, 944 F.2d at 1528 (CA9 1991) ("A decision to accept or reject an offer of

settlement is conduct incidental to the prosecution of the suit and not a separate and distinct activity which might form the basis for antitrust liability."), aff'd, 508 U.S. 49 (1993); see also *Valley Drug*, 344 F.3d at 1309 ("The failure to produce the competing [generic] drug, rather than the payment of money, is the exclusionary effect ***.").

Noerr-Pennington immunity trumps the question presented as to the Solvay and Par/Paddock settlement. The FTC cannot undo Solvay and Par/Paddock's petitioned-for consent judgment, entered by the court as a continuing-injunction enforcing their compromise terms on Par/Paddock's generic entry.

B. Under pre-MMA rules, second ANDA filer Par/Paddock could not have obtained an earlier settlement-entry date.

Par/Paddock's settlement is pro-competitive. The FTC's theory is that but-for alleged reverse-payments, each generic would have obtained an earlier settlement-entry date. FTC-Br.23-24; J.A.56 ¶¶93-94. That theory is inapplicable to second-filer Par/Paddock, whose settlement enabled entry on the *same day* as Watson, 180-days earlier than Watson's pre-MMA exclusivity period otherwise would have permitted. Pet.App.12a.

Even under the FTC's theory that a settlement enabling generic entry before patent expiration may nonetheless cause anticompetitive "delay," a purported delay could only exist if the second-filer entered more than 180-days *after* the first-filer. In the three reverse-payment cases litigated by the FTC (all involving pre-MMA ANDAs), Par/Paddock is the

only second-filer that obtained the same entry date as the first-filer.[8]

Because Par/Paddock could *not* have obtained an earlier settlement-entry date than Watson even *without* any alleged reverse-payment, the FTC can only allege: "If Solvay had settled with Watson only, Par had ample financial incentive to continue to challenge Solvay's patent." J.A.56 ¶95.

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[8]

Sept. 1, 2001 — 1st-filer entry
Jan. 1, 2004 — 2nd-filer entry
Sept. 5, 2006 — patent expiry

K-Dur

"Delay" between first- and second-filer entry = 28 months

Apr. 6, 2012 — 1st-filer entry
Oct. 3, 2012 — 2nd-filer entry
Apr. 6, 2015 — patent expiry

Provigil

"Delay" between first- and second-filer entry = 180 days

Aug. 31, 2015 — 1st-filer entry (Watson)
Aug. 31, 2015 — 2nd-filer entry (Par/Paddock)
Aug. 30, 2020 — patent expiry

AndroGel

"Delay" between first- and second-filer entry = zero

From FTC complaints susceptible of judicial notice. See *Tellabs v. Makor Issues & Rights*, 551 U.S. 308, 322 (2007).

That bears repeating: the FTC acknowledges that due to the pre-determined settlement between Solvay and first-filer Watson, Par/Paddock could *not* have obtained the FTC's theoretical earlier settlement-entry date even *absent* any alleged reverse-payment. The FTC's case against the Solvay and Par/Paddock settlement is based on a purported *duty* by second-filer Par/Paddock to have continued litigating after first-filer Watson settled.

Under pre-MMA rules for subsequent ANDA-filers, success in a continued litigation by Par/Paddock would have required winning "a final decision of a court from which no appeal *** has been or can be taken." 21 U.S.C. 355 note (explaining pre-MMA rule). In other words, Par/Paddock would have been required to win in the district court *and* sustain that victory through the Federal Circuit's infamous coin-flip reversal rate. Even then, under pre-MMA rules, *Watson* would have reaped the reward of Par/Paddock's Herculean efforts—with Par/Paddock still having to wait dutifully to enter 180-days later.

The FTC's complaint against Par/Paddock thus dangles by an allegation of "ample financial incentive" for continued-litigation when Congress enacted the MMA's remedial changes precisely because such incentives were *lacking* under pre-MMA law. *Mova Pharm.* v. *Shalala*, 140 F.3d 1060, 1073 (CADC 1998) ("One difficulty is that the 180-day exclusivity period will seemingly always go to the *first* applicant, no matter whose suit satisfies the court-decision trigger ***. It seems odd to reward the first applicant if some later applicant was the party that actually prevailed in the patent-infringement litigation.").

As a Hatch-Waxman practice manual observes:

> If the generic is not a first-filer, it will obtain no exclusivity even if the patent is held invalid or not infringed. Thus, there is little to gain by remaining a party to the litigation and continuing to pay litigation costs and endure discovery burdens. Nonlitigation alternatives should, therefore, be considered all the more seriously to avoid unnecessary litigation costs.

ANDA Litigation, *supra*, at 138.

The FTC dismisses "the competitive consequences of [Par/Paddock's] status as a second filer (as compared to Watson's status as a first filer)" as "an intricate argument." FTC-Cert.Reply-9. That intricacy derives from the FTC contending that it states an antitrust claim solely by alleging that Par/Paddock "had ample financial incentive to continue to challenge Solvay's patent." J.A.56 ¶95. Our antitrust laws do not compel firms to litigate.

CONCLUSION

The judgment below should be affirmed.

Respectfully submitted,

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APPENDIX

APPENDIX A

113TH CONGRESS
1ST SESSION S. 214

To prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market.

IN THE SENATE OF THE UNITED STATES

Ms. KLOBUCHAR (for herself, Mr. GRASSLEY, Mr. DURBIN, Mr. FRANKEN, and Mr. JOHNSON of South Dakota) introduced the following bill; which was read twice and referred to the Committee on the Judiciary.

A BILL

To prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market.

SECTION 1. SHORT TITLE.

This Act may be cited as the "Preserve Access to Affordable Generics Act".

SEC. 2. CONGRESSIONAL FINDINGS AND DECLARATION OF PURPOSES.

(a) FINDINGS.—Congress finds the following:

(1) In 1984, the Drug Price Competition and Patent Term Restoration Act (Public Law 98–417) (referred to in this Act as the "1984 Act"), was enacted with the intent of facilitating the early entry of generic drugs while preserving incentives for innovation.

(2) Prescription drugs make up 10 percent of the national health care spending but for the past decade have been one of the fastest growing segments of health care expenditures.

(3) Until recently, the 1984 Act was successful in facilitating generic competition to the benefit of consumers and health care payers—although 67 percent of all prescriptions dispensed in the United States are generic drugs, they account for only 20 percent of all expenditures.

(4) Generic drugs cost substantially less than brand name drugs, with discounts off the brand price sometimes exceeding 90 percent.

(5) Federal dollars currently account for an estimated 35 percent of the $263,000,000,000 spent on prescription drugs, and this share is expected to rise to 42 percent by 2021.

(6)(A) In recent years, the intent of the 1984 Act has been subverted by certain settlement agreements between brand companies and their potential generic competitors that make "reverse payments" which are payments by the brand company to the generic company.

(B) These settlement agreements have unduly delayed the marketing of low-cost generic drugs contrary to free competition, the interests of consumers, and the principles underlying antitrust law.

(C) Because of the price disparity between brand name and generic drugs, such agreements are more profitable for both the brand and generic manufacturers than competition, and will become increasingly common unless prohibited.

(D) These agreements result in consumers losing the benefits that the 1984 Act was intended to provide.

(b) PURPOSES.—The purposes of this Act are—

(1) to enhance competition in the pharmaceutical market by stopping anticompetitive agreements between brand name and generic drug manufacturers that limit, delay, or otherwise prevent competition from generic drugs; and

(2) to support the purpose and intent of antitrust law by prohibiting anticompetitive practices in the pharmaceutical industry that harm consumers.

SEC. 3. UNLAWFUL COMPENSATION FOR DELAY.

The Federal Trade Commission Act (15 U.S.C. 44 et seq.) is amended by—

(1) redesignating section 28 as section 29; and

(2) inserting before section 29, as redesignated, the following:

"SEC. 28. PRESERVING ACCESS TO AFFORDABLE GENERICS.

"(a) IN GENERAL.—

"(1) ENFORCEMENT PROCEEDING.—The Federal Trade Commission may initiate a proceeding to enforce the provisions of this section against the parties to any agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a drug product.

"(2) PRESUMPTION.—

"(A) IN GENERAL.—Subject to subparagraph (B), in such a proceeding, an agreement shall be presumed to have anticompetitive effects and be unlawful if—

"(i) an ANDA filer receives anything of value; and

"(ii) the ANDA filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the ANDA product for any period of time.

"(B) EXCEPTION.—The presumption in subparagraph (A) shall not apply if the parties to such agreement demonstrate by clear and convincing evidence that the procompetitive

benefits of the agreement outweigh the anti-competitive effects of the agreement.

"(b) COMPETITIVE FACTORS.—In determining whether the settling parties have met their burden under subsection (a)(2)(B), the fact finder shall consider—

"(1) the length of time remaining until the end of the life of the relevant patent, compared with the agreed upon entry date for the ANDA product;

"(2) the value to consumers of the competition from the ANDA product allowed under the agreement;

"(3) the form and amount of consideration received by the ANDA filer in the agreement resolving or settling the patent infringement claim;

"(4) the revenue the ANDA filer would have received by winning the patent litigation;

"(5) the reduction in the NDA holder's revenues if it had lost the patent litigation;

"(6) the time period between the date of the agreement conveying value to the ANDA filer and

the date of the settlement of the patent infringement claim; and

"(7) any other factor that the fact finder, in its discretion, deems relevant to its determination of competitive effects under this subsection.

"(c) LIMITATIONS.—In determining whether the settling parties have met their burden under subsection (a)(2)(B), the fact finder shall not presume—

"(1) that entry would not have occurred until the expiration of the relevant patent or statutory exclusivity; or

"(2) that the agreement's provision for entry of the ANDA product prior to the expiration of the relevant patent or statutory exclusivity means that the agreement is pro-competitive, although such evidence may be relevant to the fact finder's determination under this section.

"(d) EXCLUSIONS.—Nothing in this section shall prohibit a resolution or settlement of a patent infringement claim in which the consideration granted by the NDA holder to the ANDA filer as part

of the resolution or settlement includes only one or more of the following:

"(1) The right to market the ANDA product in the United States prior to the expiration of—

"(A) any patent that is the basis for the patent infringement claim; or

"(B) any patent right or other statutory exclusivity that would prevent the marketing of such drug.

"(2) A payment for reasonable litigation expenses not to exceed $7,500,000.

"(3) A covenant not to sue on any claim that the ANDA product infringes a United States patent.

"(e) REGULATIONS AND ENFORCEMENT.—

"(1) REGULATIONS.—The Federal Trade Commission may issue, in accordance with section 553 of title 5, United States Code, regulations implementing and interpreting this section. These regulations may exempt certain types of agreements described in subsection (a) if the Commission determines such agreements will

further market competition and benefit consumers. Judicial review of any such regulation shall be in the United States District Court for the District of Columbia pursuant to section 706 of title 5, United States Code.

"(2) ENFORCEMENT.—A violation of this section shall be treated as a violation of section 5.

"(3) JUDICIAL REVIEW.—Any person, partnership or corporation that is subject to a final order of the Commission, issued in an administrative adjudicative proceeding under the authority of subsection (a)(1), may, within 30 days of the issuance of such order, petition for review of such order in the United States Court of Appeals for the District of Columbia Circuit or the United States Court of Appeals for the circuit in which the ultimate parent entity, as defined at 16 CFR 801.1(a)(3), of the NDA holder is incorporated as of the date that the NDA is filed with the Secretary of the Food and Drug Administration, or the United States Court of Appeals for the circuit in which the ultimate parent entity of the ANDA filer is incorporated as of the date that the ANDA is filed with the Secretary of the Food and Drug

Administration. In such a review proceeding, the findings of the Commission as to the facts, if supported by evidence, shall be conclusive.

"(f) ANTITRUST LAWS.—Nothing in this section shall be construed to modify, impair or supersede the applicability of the antitrust laws as defined in subsection (a) of the 1st section of the Clayton Act (15 U.S.C. 12(a)) and of section 5 of this Act to the extent that section 5 applies to unfair methods of competition. Nothing in this section shall modify, impair, limit or supersede the right of an ANDA filer to assert claims or counterclaims against any person, under the antitrust laws or other laws relating to unfair competition.

"(g) PENALTIES.—

"(1) FORFEITURE.—Each person, partnership or corporation that violates or assists in the violation of this section shall forfeit and pay to the United States a civil penalty sufficient to deter violations of this section, but in no event greater than 3 times the value received by the party that is reasonably attributable to a violation of this section. If no such value has been received by the

NDA holder, the penalty to the NDA holder shall be sufficient to deter violations, but in no event greater than 3 times the value given to the ANDA filer reasonably attributable to the violation of this section. Such penalty shall accrue to the United States and may be recovered in a civil action brought by the Federal Trade Commission, in its own name by any of its attorneys designated by it for such purpose, in a district court of the United States against any person, partnership or corporation that violates this section. In such actions, the United States district courts are empowered to grant mandatory injunctions and such other and further equitable relief as they deem appropriate.

"(2) CEASE AND DESIST.—

"(A) IN GENERAL.—If the Commission has issued a cease and desist order with respect to a person, partnership or corporation in an administrative adjudicative proceeding under the authority of subsection (a)(1), an action brought pursuant to paragraph (1) may be commenced against such person, partnership or corporation at any time before the

expiration of one year after such order becomes final pursuant to section 5(g).

"(B) EXCEPTION.—In an action under subparagraph (A), the findings of the Commission as to the material facts in the administrative adjudicative proceeding with respect to such person's, partnership's or corporation's violation of this section shall be conclusive unless—

"(i) the terms of such cease and desist order expressly provide that the Commission's findings shall not be conclusive; or

"(ii) the order became final by reason of section 5(g)(1), in which case such finding shall be conclusive if supported by evidence.

"(3) CIVIL PENALTY.—In determining the amount of the civil penalty described in this section, the court shall take into account—

"(A) the nature, circumstances, extent, and gravity of the violation;

"(B) with respect to the violator, the degree of culpability, any history of violations, the

ability to pay, any effect on the ability to continue doing business, profits earned by the NDA holder, compensation received by the ANDA filer, and the amount of commerce affected; and

"(C) other matters that justice requires.

"(4) REMEDIES IN ADDITION.—Remedies provided in this subsection are in addition to, and not in lieu of, any other remedy provided by Federal law. Nothing in this paragraph shall be construed to affect any authority of the Commission under any other provision of law.

"(h) DEFINITIONS.—In this section:

"(1) AGREEMENT.—The term 'agreement' means anything that would constitute an agreement under section 1 of the Sherman Act (15 U.S.C. 1) or section 5 of this Act.

"(2) AGREEMENT RESOLVING OR SETTLING A PATENT INFRINGEMENT CLAIM.—The term 'agreement resolving or settling a patent infringement claim' includes any agreement that is entered into within 30 days of the resolution or

the settlement of the claim, or any other agreement that is contingent upon, provides a contingent condition for, or is otherwise related to the resolution or settlement of the claim.

"(3) ANDA.—The term 'ANDA' means an abbreviated new drug application, as defined under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

"(4) ANDA FILER.—The term 'ANDA filer' means a party who has filed an ANDA with the Food and Drug Administration.

"(5) ANDA PRODUCT.—The term 'ANDA product' means the product to be manufactured under the ANDA that is the subject of the patent infringement claim.

"(6) DRUG PRODUCT.—The term 'drug product' means a finished dosage form (e.g., tablet, capsule, or solution) that contains a drug substance, generally, but not necessarily, in association with 1 or more other ingredients, as defined in section 314.3(b) of title 21, Code of Federal Regulations.

"(7) NDA.—The term 'NDA' means a new drug application, as defined under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)).

"(8) NDA HOLDER.—The term 'NDA holder' means—

"(A) the party that received FDA approval to market a drug product pursuant to an NDA;

"(B) a party owning or controlling enforcement of the patent listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the 'FDA Orange Book') in connection with the NDA; or

"(C) the predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with any of the entities described in subparagraphs (A) and (B) (such control to be presumed by direct or indirect share ownership of 50 percent or greater), as well as the licensees, licensors, successors, and assigns of each of the entities.

"(9) PATENT INFRINGEMENT.—The term 'patent infringement' means infringement of any patent or of any filed patent application, extension, reissue, renewal, division, continuation, continuation in part, reexamination, patent term restoration, patents of addition and extensions thereof.

"(10) PATENT INFRINGEMENT CLAIM.—The term 'patent infringement claim' means any allegation made to an ANDA filer, whether or not included in a complaint filed with a court of law, that its ANDA or ANDA product may infringe any patent held by, or exclusively licensed to, the NDA holder of the drug product.

"(11) STATUTORY EXCLUSIVITY.—The term 'statutory exclusivity' means those prohibitions on the approval of drug applications under clauses (ii) through (iv) of section 505(c)(3)(E) (5- and 3-year data exclusivity), section 527 (orphan drug exclusivity), or section 505A (pediatric exclusivity) of the Federal Food, Drug, and Cosmetic Act.".

SEC. 4. NOTICE AND CERTIFICATION OF AGREEMENTS.

(a) NOTICE OF ALL AGREEMENTS.—Section 1112(c)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. 355 note) is amended by—

(1) striking "the Commission the" and inserting the following: "the Commission—

"(1) the";

(2) striking the period and inserting "; and"; and

(3) inserting at the end the following:

"(2) any other agreement the parties enter into within 30 days of entering into an agreement covered by subsection (a) or (b).".

(b) CERTIFICATION OF AGREEMENTS.—Section 1112 of such Act is amended by adding at the end the following:

"(d) CERTIFICATION.—The Chief Executive Officer or the company official responsible for negotiating any agreement required to be filed under subsection

(a), (b), or (c) shall execute and file with the Assistant Attorney General and the Commission a certification as follows: 'I declare that the following is true, correct, and complete to the best of my knowledge: The materials filed with the Federal Trade Commission and the Department of Justice under section 1112 of subtitle B of title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, with respect to the agreement referenced in this certification: (1) represent the complete, final, and exclusive agreement between the parties; (2) include any ancillary agreements that are contingent upon, provide a contingent condition for, or are otherwise related to, the referenced agreement; and (3) include written descriptions of any oral agreements, representations, commitments, or promises between the parties that are responsive to subsection (a) or (b) of such section 1112 and have not been reduced to writing.'.".

SEC. 5. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.

Section 505(j)(5)(D)(i)(V) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V)) is amended by inserting "section 28 of the Federal

Trade Commission Act or" after "that the agreement has violated".

SEC. 6. COMMISSION LITIGATION AUTHORITY.

Section 16(a)(2) of the Federal Trade Commission Act (15 U.S.C. 56(a)(2)) is amended—

(1) in subparagraph (D), by striking "or" after the semicolon;

(2) in subparagraph (E), by inserting "or" after the semicolon; and

(3) inserting after subparagraph (E) the following:

"(F) under section 28;".

SEC. 7. STATUTE OF LIMITATIONS.

The Commission shall commence any enforcement proceeding described in section 28 of the Federal Trade Commission Act, as added by section 3, except for an action described in section 28(g)(2) of the Federal Trade Commission Act, not later than 3 years after the date on which the parties to the agreement file the Notice of Agreement as provided

by sections 1112(c)(2) and (d) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (21 U.S.C. 355 note).

SEC. 8. SEVERABILITY.

If any provision of this Act, an amendment made by this Act, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made by this Act, and the application of the provisions of such Act or amendments to any person or circumstance shall not be affected thereby.

APPENDIX

APPENDIX B

Par Pharmaceutical
Companies, Inc.
300 Tice Boulevard
Woodcliff Lake, NJ 07677
tel 201 802 4000
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www.parpharm.com

FOIA EXEMPT
CONFIDENTIAL BUSINESS INFORMATION

BY HAND

November 22, 2010

Federal Trade Commission
Premerger Notification Office
Bureau of Competition
Room 303
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

U.S. Department of Justice
Director of Operations &
Civil Enforcement
Antitrust Division
950 Pennsylvania Avenue, N.W., #3335
Washington, DC 20530

Re: Filing Pursuant to Section 1112(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

Dear Sir or Madam:

Pursuant to Section 1112(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Par Pharmaceutical Companies, Inc. ("Par") files the enclosed First Amendment to Co-Promotion Agreement entered into on November 10, 2010 with Abbott Laboratories f/k/a Solvay Pharmaceuticals, Inc. This First Amendment amends the September 13, 2006 Co-Promotion Agreement, which Par submitted to the FTC and DOJ pursuant to Section 1112(a) on September 25, 2006. We also include a November 19, 2010 letter from Par to Abbott Laboratories pursuant to the First Amendment. The effect of the First Amendment and the ensuing November 15, 2010 letter is to terminate the Co-Promotion Agreement. For your convenience, the September 13, 2006 Co-Promotion Agreement also is enclosed.

This letter and the copy of the First Amendment to the Co-Promotion Agreement enclosed herewith are being produced pursuant to the requirements of the Medicare Modernization Act, Pub. L. 108-173 Title XI, Subtitle B, §§ 1111-1118 (codified at 21 U.S.C. § 355 (note)). We request confidential treatment of all materials submitted pursuant to 15 U.S.C. § 18a(h), the Commission's and Division's regulations protecting confidential proprietary information from disclosure, and any other relevant confidentiality provisions under federal and state law.

Very truly yours,
/s/ Martin L. Wilson
Martin L. Wilson
Senior Director – Legal,
Compliance
Par Pharmaceutical
Companies, Inc.

Enclosures

RESPONDENT'S BRIEF

SUPREME COURT, U.S.
FILED
NOV 13 2012
OFFICE OF THE CLERK
SUPREME COURT, U.S.

No. 12-416

IN THE
Supreme Court of the United States

FEDERAL TRADE COMMISSION,
Petitioner,

v.

WATSON PHARMACEUTICALS, INC., ET AL.,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF FOR RESPONDENT SOLVAY PHARMACEUTICALS, INC.

DO NOT REMOVE FROM LL RR

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November 13, 2012

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

QUESTION PRESENTED

Whether the settlement of bona fide Hatch-Waxman patent litigation in which the accused generic infringer is licensed to come to market before the expiration of the brand-name drug company's patent and which does not exceed the exclusionary potential of the patent is not rendered presumptively illegal merely because it also includes a business deal that is alleged to provide additional value to the accused infringer.

RULE 29.6 STATEMENT

Respondent Solvay Pharmaceuticals, Inc., now known as AbbVie Products LLC, is a wholly owned indirect subsidiary of Abbott Laboratories. No person beneficially owns 10% or more of the outstanding shares of Abbott Laboratories.

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BRIEF FOR RESPONDENT SOLVAY PHARMACEUTICALS, INC.

Respondent Solvay Pharmaceuticals, Inc. (Solvay) respectfully acquiesces in the petition for a writ of certiorari. Because this case is a better vehicle for resolving the circuit split than is the *K-Dur* case (Nos. 12-245 and 12-265), Solvay agrees with the FTC that the Court should grant certiorari in this case rather than in *K-Dur*. Alternatively, Solvay respectfully suggests that the Court grant certiorari in both cases.

INTRODUCTION

The FTC's petition identifies a clear circuit split on an issue of national importance. Although Solvay believes that the decision below by the Eleventh Circuit was correct, and thus disagrees with the FTC on the merits, Solvay agrees that the petition should be granted.

This case presents the question whether holders of some types of pharmaceutical patents have fewer rights to enforce their patents than do other patentees, merely because their patents cover new pharmaceuticals. Here, the manufacturer of an innovative drug covered by a patent expiring in 2020 sued would-be generic manufacturers for infringement. That bona fide dispute was settled, after years of hard-fought litigation, by splitting the remaining patent term: the innovator licensed the would-be generic manufacturers to market their allegedly infringing products five years early, in 2015, and the generic manufacturers agreed to respect the patent and not launch their allegedly infringing drugs until then. The FTC does not quarrel with this patent term split. Rather, the FTC contends that the

settlement should be presumed anticompetitiv solely because the parties also simultaneously en tered into promotion and manufacturing agreement

In the decision below, the Eleventh Circuit held, i agreement with every appellate court that had con fronted this issue, that this litigation settlement di not violate the antitrust laws' prohibition of unrea sonable restraints of trade because the patent ha the *potential* to exclude the allegedly infringing g neric competition from the market for five yea longer than the settlement will. In other words, th only supposed anticompetitive effect of the settl ment—restricting allegedly infringing competitio until 2015—is within the rights granted by issuan of the patent. This holding correctly reflected the ex clusionary right that is at the heart of a presum tively valid patent.

Since then, however, the Third Circuit has artic lated a directly contrary rule, holding in a differe case that a settlement of Hatch-Waxman patent lit gation that is accompanied by a "payment" presum tively violates the antitrust laws and subjects th settling parties to treble-damage liability. The im pact of the Third Circuit's decision will be enormo because the FTC and private plaintiffs can choose bring many antitrust challenges to pharmaceutic patent settlements within the Third Circuit. Th decision threatens to slow the development of bo innovative products and low-cost generics. The dec sion also creates the potential for massive and pun tive liability based upon conduct that, when take had been sanctioned by the federal courts. This i sue warrants this Court's intervention. The FTC petition should be granted.

STATEMENT OF THE CASE

1. Unimed Pharmaceuticals, Inc. (Unimed), which Solvay has since acquired, and its joint-development partner, Besins Healthcare, S.A. (Besins), invented AndroGel and discovered through years of clinical testing that AndroGel is a safe and effective treatment for men who suffer from symptoms of low testosterone. AndroGel has been available since 2000, when the FDA approved Unimed's New Drug Application (NDA). Second Amended Complaint (Complaint) ¶¶ 31-33. In January 2003, the U.S. Patent and Trademark Office (PTO) issued U.S. Patent No. 6,503,894 ('894 patent), which expressly discloses the AndroGel formulation. The patent expires in August 2020. *Id.* ¶¶ 39-43. AndroGel has become a great medical and commercial success, providing needed treatment to millions of patients and generating nearly $875 million in sales in 2011.[1]

2. Although Unimed invested significant time and money establishing in clinical trials that AndroGel is safe and effective, a manufacturer seeking to introduce a generic version of AndroGel need not do so. The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly called the Hatch-Waxman Act, changed the law to permit a generic manufacturer to obtain FDA approval by filing an Abbreviated New Drug Application (ANDA) relying on the innovator's proprietary clinical trial data to establish safety and efficacy, as long as the generic manufacturer shows that its proposed drug has the same active ingredient

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[1] Abbott Labs., *2011 Annual Report* 52, www.abbott.com/static/content/microsite/annual_report/2011/downloads/Abbott_AR2011_Full.pdf.

as and is bioequivalent to the innovator drug. 2 U.S.C. § 355(j)(2)(A) (2000); *PLIVA, Inc. v. Mensing* 131 S. Ct. 2567, 2574 (2011).[2] Companies thus ca develop generic drugs much more quickly an cheaply than if they had to conduct their own clinica trials. *PLIVA*, 131 S. Ct. at 2574.

The Hatch-Waxman Act encourages patent dis putes between innovator and generic drug companie to be resolved quickly and before the generic com pany has come to market. The Act requires innova tor companies to provide public notice of any patent that cover their drugs, by listing those patents in a FDA publication commonly called the Orange Boo 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53. Th FDA may not approve the marketing of a generic b fore expiration of any patent listed in the Orang Book as covering the drug unless the ANDA contair a "paragraph IV certification" alleging that the liste patent is invalid or unenforceable, will not be i fringed by the proposed generic drug, or both. 2 U.S.C. § 355(j)(2)(A)(vii)(IV). The statute encourag paragraph IV certifications by making the first fil for a generic drug eligible for 180 days of market e clusivity against other generic applicants. *I* § 355(j)(5)(B)(iv). This exclusivity can be worth mi lions of dollars.

The Hatch-Waxman Act also deems the mere filir of a paragraph IV certification an act of pate infringement, so that the innovator can file a

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[2] Portions of 21 U.S.C. § 355 were amended by Title XI of t Medicare Prescription Drug, Improvement, and Modernizati Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, 2448, but t amendments generally do not apply to the ANDAs at issue this case. *Id.* §§ 1101(c), 1102(b), 117 Stat. at 2456, 2460 (effe tive date provisions).

immediate patent lawsuit against the ANDA filer. 35 U.S.C. § 271(e)(2)(A). To further encourage these pre-marketing lawsuits, the Hatch-Waxman Act imposes a 30-month stay on FDA approval of an ANDA if, but only if, the innovator company sues within 45 days of receiving notice of a paragraph IV certification. 21 U.S.C. § 355(j)(5)(B)(iii). If the innovator prevails in such a lawsuit, it is entitled as a matter of right to an injunction prohibiting ANDA approval before the patent expires. *Id.* § 355(j)(5)(B)(iii)(II); 35 U.S.C. § 271(e)(4)(A). The innovator cannot recover damages unless the generic company has commercially launched its product before the district court's judgment—a rare occurrence because FDA approval is stayed for 30 months and because a generic company typically will be deterred by the potential for a ruinous damages award if it ultimately were to lose the patent suit. 35 U.S.C. § 271(e)(4); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990).

3. In May 2003, Watson Pharmaceuticals, Inc. (Watson) and Paddock Laboratories, Inc. (Paddock) each filed an ANDA seeking FDA approval to market a generic version of AndroGel. Each ANDA contained a paragraph IV certification against the '894 patent, and Unimed and Besins promptly filed patent infringement lawsuits against Watson and Paddock in the United States District Court for the Northern District of Georgia. Complaint ¶¶ 44, 47.

The patent litigations proceeded vigorously for more than three years. The parties produced hundreds of thousands of pages of documents, took nearly 40 depositions, and retained numerous scientific experts. Pet. App. 33a. Paddock's litigation was so resource-intensive that it had to seek litigation funding from a larger generic drug company, Par

Pharmaceutical Companies, Inc. (Par), and in e change gave Par the exclusive right to distribu Paddock's generic version of AndroGel if and when received FDA approval and could come to marke Complaint ¶ 46.

Unimed's patent was specifically intended to cov AndroGel and described AndroGel's compositio Watson and Paddock each conceded that its respe tive product used the same ingredients in ve nearly the same amounts as AndroGel. As is cor mon in high-stakes patent litigation, however, ea defendant raised numerous other defenses. Ea contended, for example, that the patent's claims d not actually cover AndroGel because of technical e rors in claim drafting, even though the PTO had i sued a certificate of correction resolving those erro and even though the patent stated that AndroG was the preferred embodiment. *Cf. Topliff v. Topli* 145 U.S. 156, 171 (1892) ("The object of the pate law is to secure to inventors a monopoly of what th have actually invented or discovered, and it oug not to be defeated . . . by the application of artifici rules of interpretation."); *Vitronics Corp. v. Conce tronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) (co struing a patent's claims to exclude the preferr embodiment "is rarely, if ever, correct"). Watson a Paddock also contended that the patent was invali They filed partial summary judgment motions, b those motions did not address every asserted claim the patent and therefore could not have disposed the cases even if they had been granted.

The district court has since expressly held, in t subsequent antitrust class-action litigation discuss below, that Unimed's claims in the patent litigati were bona fide, and that Unimed's litigati

positions were objectively reasonable. *In re AndroGel Antitrust Litig. (No. II)*, 2012 WL 5352986 (N.D. Ga. Oct. 30, 2012), *appeal docketed*, No. 12-15562-B (11th Cir. Oct. 30, 2012).

4. In September 2006, after three years of hard-fought litigation and before the district court decided any substantive motions, the parties settled. As part of each settlement, Solvay (Unimed's parent company) agreed to license the respective generic company to launch its generic version of AndroGel in August 2015—five years before the '894 patent will expire. Complaint ¶¶ 65, 76. In exchange, each generic company agreed to respect the '894 patent by not marketing its generic drug before 2015. Also, Watson, Paddock, and Par each agreed to provide services to Solvay—Watson to promote AndroGel to urologists, Paddock to provide manufacturing capacity for AndroGel, and Par to promote AndroGel to primary care physicians—and Solvay agreed to pay for those services. *Id.* ¶¶ 66, 74. Although the FTC alleged that Solvay overpaid for these services, there was no allegation that the services were not provided.

5. After the settlements, the FTC began what became a two-year investigation into whether the settlements violated the antitrust laws. Following extensive discovery, the FTC filed a lawsuit against respondents in the United States District Court for the Central District of California. Shortly thereafter, several private plaintiffs brought putative class actions involving substantively identical allegations. Over the FTC's and the private plaintiffs' objection, the court transferred the litigation to the United States District Court for the Northern District of

Georgia, which had presided over the patent litigation.

Following the transfer, the FTC filed its operative complaint. The FTC alleged that Solvay's business agreements with Watson, Par, and Paddock were not "independent business transactions," and that Solvay overpaid. The FTC alleged that Solvay entered into the business arrangements because Watson, Par, and Paddock otherwise would have insisted on an earlier date for their licenses to market generic AndroGel. Complaint ¶¶ 81-85. The FTC did not allege that Solvay's patent suits were unreasonable "sham" litigation, but instead only that Solvay was "not likely to prevail" in its patent infringement lawsuits. *Id.* ¶ 86. The FTC alleged that both settlements violated section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a). Complaint ¶¶ 106-112. The FTC calls any "compensation" given by an innovative drug manufacturer to a generic company as part of a settlement of Hatch-Waxman Act patent litigation—other than a license to enter with a generic version before expiration of the patent—a "reverse payment." Pet. 2.

6. The district court rejected the FTC's argument that "it should be presumptively unlawful for companies to settle a patent dispute with reverse payments," Pet. App. 51a, and dismissed the FTC's complaint. The court noted that "neither the rule of reason nor the per se analysis is appropriate when a patent settlement is involved" because these approaches "look at whether the challenged conduct had an anticompetitive effect on the market." *Id.* at 47a-48a (internal quotation marks omitted). The entire purpose of a patent, however, is to "create an environment of exclusion" and "cripple competition"

within the patent's exclusionary scope; "[t]he anti-competitive effect is already present" by virtue of the patent's existence. *Id.* at 48a (internal quotation marks omitted). Because the FTC did not allege that the settlements exceeded the '894 patent's exclusionary potential, the district court concluded that the FTC did not state an antitrust claim.[3]

7. The court of appeals affirmed. The court began its opinion by observing that the business of innovator drug companies is to participate in an innovation lottery. These companies typically spend billions of dollars and many years on research for each product they bring to market. Protecting their ability to generate profits by obtaining patents and charging commensurate prices for the life of their patents is vital to the development of new pharmaceutical products because "[n]o rational actor would take that kind of a risk over that period of time without the prospect of a big reward." Pet. App. 2a.

With due regard for the "tension between the pro-exclusivity tenets of patent law and the pro-competition tenets of antitrust law," *id.* at 16a, the court of appeals noted that "antitrust laws typically prohibit agreements where one company pays a potential competitor not to enter the market." *Id.* at 17a. But it also observed that patent litigation

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[3] The district court also dismissed the private plaintiffs' claims that respondents' litigation settlements violated the Sherman Act, but it did not dismiss the private plaintiffs' claims that alleged, unlike the FTC, that Unimed's '894 patent litigation was a sham, brought without any reasonable basis and for an improper purpose. As noted above, the district court has since granted summary judgment to respondents, holding that the patent litigation was not a sham. *AndroGel*, 2012 WL 5352986.

settlements are "atypical cases" because a patent "a 'lawful right to exclude others' from the marke *Id.* (quoting *Valley Drug Co. v. Geneva Pharms., In* 344 F.3d 1294, 1304 (11th Cir. 2003)). The cou held that there cannot be antitrust liability for supposed "exclusionary" effect that is within the e clusionary potential of the patent. The appropria antitrust rule of decision, therefore, "is an evaluati of whether the settlement agreements contain pro sions that restrict competition beyond the scope the exclusionary potential of the patent" becau that rule "giv[es] full force to the exclusionary righ [the patent] potentially conveyed." *Id.* at 23a-24a.

The court of appeals rejected the relevance of t FTC's allegation that Solvay was "not likely to pr vail" in the patent litigation. The FTC proposed th antitrust liability turn on the "likely exclusionary fect" of the patent, rather than its "potential excl sionary effect." *Id.* at 30a. The court explained th this "retrospective predict-the-likely-outcome-tha never-came" standard would be impractical becau it would require courts in antitrust cases challengi patent litigation settlements to undertake the "t ducken task" of "attempt[ing] to decide how so other court in some other case at some other tir was likely to have resolved some other claim if it h been pursued to [a] judgment" that was never re dered. *Id.* at 33a, 36a. Such a task would require litigating the entire patent case in an effort to d termine who the likely winner would have been. T court of appeals explained that this would burdensome for the parties and the court, wou "undo much of the benefit of settling the patent li gation" in the first place, and so would "discoura settlements." *Id.* at 33a. More importantly, such "retrospective prediction" of success is "unlikely to

reliable," as the FTC had itself "recognized . . . in the past." *Id.* Treble-damage antitrust liability should not turn on what essentially would be guesswork.

The court of appeals emphasized that the "reality of patent litigation and the risks it presents to the patent holder" are likely to motivate the patent holder to prefer settling "even if it might well prevail." *Id.* at 31a. The court recognized that "[e]ven the confident patent owner knows that . . . prevailing in patent litigation" is rarely if ever assured, *id.* at 32a, and that even "[a] party likely to win might not want to play the odds for the same reason that one likely to survive a game of Russian roulette might not want to take a turn," *id.* at 30a.

The court of appeals also rejected the FTC's alternative argument, *see* FTC Opening Br. at 43-56, *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298 (11th Cir. 2012) (No. 10-12729-DD) (filed July 26, 2010), that all "reverse-payment" settlements should be presumed unlawful. Pet. App. 4a.

The FTC sought rehearing en banc, which the court of appeals denied. *Id.* at 62a-63a. The FTC's petition followed.

ARGUMENT

A. The Petition Presents A Question On Which A Circuit Conflict Has Arisen Since The Decision Below Was Rendered And On Which National Uniformity Is Critically Important

1. The decision below accorded with the decisions of every appellate court in the country to have addressed the question presented, as well as every non-appealed district court decision on the subject. These

courts uniformly held that a company's agreemen not to market its generic drug in settlement o Hatch-Waxman patent litigation does not violate th antitrust laws—regardless of whether it is accompa nied by an alleged "reverse payment"—so long as th limitation on marketing is within the exclusionar potential of the patent, the patent was not procure by fraud, and the patent litigation was not a sham Although some courts did hold that particular "re verse-payment" settlements were or might have bee unlawful, these courts did so because the particula settlements restrained competition beyond the exclu sionary potential of the patent.[5]

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[4] *See Ark. Carpenters Health & Welfare Fund v. Bayer A(* 604 F.3d 98, 105 (2d Cir. 2010); *In re Tamoxifen Citrate Ant trust Litig.*, 466 F.3d 187, 205-09 (2d Cir. 2006); *In re Ciproflo acin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1327, 133 37 (Fed. Cir. 2008); *King Drug Co. of Florence v. Cephalon, Inc* 702 F. Supp. 2d 514, 528 (E.D. Pa. 2010); *Asahi Glass Co. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986 (N.D. Ill. 200 (Posner, J., by designation); *In re Cipro Cases I & II*, 134 Ca Rptr. 3d 165, 184-86 (Ct. App. 2011), *review granted*, 269 P.3 653 (Cal. 2012); *see also In re K-Dur Antitrust Litig.*, 2009 W 508869, at *24 (D.N.J. Feb. 6, 2009), *adopted by* 2010 W 1172995 (D.N.J. Mar. 25, 2010), *rev'd*, 686 F.3d 197 (3d Ci 2012).

[5] *See Andrx Pharms., Inc. v. Elan Corp., PLC*, 421 F.3d 122 1231 (11th Cir. 2005) (settling generic company's retention its 180 days of exclusivity "had the effect of preventing any g neric competition," even by companies not party to the litig tion); *Valley Drug*, 344 F.3d at 1311-12 (settlement agreeme was not limited to potentially infringing products and used 18 day exclusivity to block other potential entrants); *In re Car izem CD Antitrust Litig.*, 332 F.3d 896, 907-08 & n.13 (6th C 2003) (same); *King Drug*, 702 F. Supp. 2d at 530-33 (sam *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 806- (D.C. Cir. 2001) (involving the same settlement agreement *Cardizem*); *see also* U.S. Br. at 16-18, *FTC v. Schering-Plou*

Two months after the decision below, this judicial uniformity came to an end. In *In re K-Dur Antitrust Litigation*, 686 F.3d 197 (3d Cir. 2012), the Third Circuit rejected the holdings of the Second, Eleventh, and Federal Circuits—including an Eleventh Circuit decision regarding the same settlement agreements the Third Circuit was evaluating. After relying on selected bits of legislative history to conclude that "[t]he goal of the Hatch-Waxman Act is to increase the availability of low cost generic drugs," the Third Circuit further concluded that "reverse-payment" settlements tend to undermine that goal and that the uniform holdings of the other circuits reflected "bad policy." *Id.* at 217. The court held that "reverse payments" should be subjected to a "quick look rule of reason analysis" and be regarded "as *prima facie* evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit." *Id.* at 218. Remarkably, the Third Circuit stated that its condemnation of "reverse-payment" patent settlements did not have general application, but instead was specifically "limited to reverse payments between patent holders and would be generic competitors in the pharmaceutical industry." *Id.* at 216.

2. The Court should grant the petition and resolve the question presented because the Third Circuit's novel holding, if allowed to stand, will have nationwide effects on respondents and on the pharmaceutical industry generally. Because of the antitrust laws' permissive venue provisions, *see* 15 U.S.C. §§ 22, 53(a), governmental and class-action plaintiffs will

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Corp., 548 U.S. 919 (2006) (No. 05-273) (filed May 17, 2006) (noting the absence of a circuit conflict at the time).

engage in forum shopping by filing all antitrust litigation regarding Hatch-Waxman patent settlements in the Third Circuit. *See, e.g.*, Jon Leibowitz, Chairman, FTC, Remarks Prepared for Delivery at the Sixth Annual Georgetown Law Global Antitrust Enforcement Symposium 4 (Sept. 19, 2012), www.ftc.gov/speeches/leibowitz/120919jdlgeorgetownspeech.pdf (announcing that the FTC will "simply be forced to bring pay-for-delay cases in the Third Circuit for years to come" if this Court does not grant certiorari). There will also be a flood of venue-transfer litigation, at least until the circuit conflict is resolved.

Moreover, a large number of settlement agreements may be subject to challenge by the FTC and class-action plaintiffs under the Third Circuit's rule. *See* Bureau of Competition, FTC, *Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, at 2 (2011), www.ftc.gov/os/2011/10/1110mmaagree.pdf (characterizing 78 settlements between 2009 and 2011 as potentially involving "reverse payments"). Many of the class-action challenges will include astronomical damages claims, in light of the antitrust laws' provision for treble damages and the generally higher pricing of brand-name drugs that is necessary to recoup the billions of dollars invested in researching and developing them. In the private suits that followed this case alone, the direct purchasers of AndroGel claimed in the district court that they were entitled to billions of dollars on their federal antitrust claims. The sum claimed dwarfs the cumulative profits Solvay has made on AndroGel since its launch, and far exceeds the combined 2011 profits of all four respondents. The companies would be exposed to this massive liability for

settling time-consuming, expensive, and difficult patent cases, even though those settlements accorded with legal standards adopted by every circuit that had considered the issue at the time the settlements occurred.

B. The Decision Below Should Be Affirmed

1. The Eleventh Circuit's decision correctly reflects the exclusionary right that is at the heart of a presumptively valid patent

In deciding whether the antitrust laws prohibit the owner of a patent from entering into a contract that would be illegal absent the patent, this Court held over half a century ago that a patentee is exempt from the antitrust laws so long as the patentee does not use its patent to reach "beyond the limits of the patent monopoly." *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948). Within the patent's limits, however, the "right to exclude others" is the "essence of a patent grant." *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980). That grant, moreover, is presumed valid until affirmatively proved otherwise. 35 U.S.C. § 282(a).

The antitrust laws proscribe "misuse of patent rights." *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 176 (1965). But they do not "reach monopolies practiced under patents" even if the patents "may turn out to be voidable under one or more of the numerous technicalities" of patent law. *Id.* at 180 (Harlan, J., concurring). Moreover, when the true scope of a patent is subject to "legitimately conflicting claims . . . , a settlement by agreement, rather than litigation, is not precluded"

by the antitrust laws. *Standard Oil Co. v. United States*, 283 U.S. 163, 171 (1931).

The Eleventh Circuit followed these well-established principles.[6] If Unimed had won its patent infringement lawsuits, the district court would have ordered the FDA not to approve Watson and Paddock's generic versions of AndroGel until at least August 2020. *See* 35 U.S.C. § 271(e)(4)(A). Such a court order—the epitome of lawful exclusion—was entirely within the realm of realistic outcomes in the litigation, as the district court has since explicitly found and as the FTC has not contested.

The settlement agreements that the FTC has challenged here plainly permit more generic competition, and create less exclusion, than would have been ordered if Unimed had won its lawsuits. The allegation that Solvay paid for this result does not alter that Solvay agreed to *less* exclusion than it lawfully and realistically might have obtained in the exercise of its constitutionally protected right to assert its patent reasonably. Because the settlements are no more exclusionary than the exclusionary potential of the patent, they do not violate the antitrust laws.

2. The rule advocated by the FTC and adopted by the Third Circuit in *K-Dur* is wrong and unworkable

a. The FTC reasons, as did the Third Circuit, that "reverse-payment" patent settlements are found only in the pharmaceutical industry and merit a unique antitrust rule of decision. Pet. 27 (arguing that "reverse payments" are "scarcely an essential or tra-

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[6] The Eleventh Circuit also properly identified many practical difficulties with the FTC's proposed rule. Pet. App. 31a-36a.

ditional feature of settlement practice" and "largely unknown outside the Hatch-Waxman context"); *K-Dur*, 686 F.3d at 208 (stating that "reverse payments" are "unique to the Hatch-Waxman context"). This view is incorrect. Many if not most patent litigation settlements entail consideration that flows from the patentee to the alleged infringer—"reverse payments," in the FTC's lexicon—with no antitrust ramifications at all. Settlements in Hatch-Waxman litigation may differ in appearance, but they do not differ in economic substance, and only the latter should be legally significant. *See Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 887-88 (2007) (criticizing antitrust rules that are "based on 'formalistic' legal doctrine rather than 'demonstrable economic effect'" (quoting *Cont'l T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 58-59 (1977))).

In a traditional patent infringement lawsuit brought under 35 U.S.C. § 271(a)-(c), the patentee seeks damages, *id.* § 284, among other possible remedies. Such litigation commonly settles with the patentee's giving up all or part of its damage claim in exchange for the infringer's agreeing to respect the plaintiff's patent and exit the market for some or all of the patent term. Settlement on these terms rarely if ever implicates the antitrust laws. *See* 1 Herbert Hovenkamp et al., *IP and Antitrust* § 7.4a, at 7-23 (2d ed. 2003 & Supp. 2010) (litigation settlements in which "the plaintiff settles by giving the defendant a nonexclusive license to practice the patent in exchange for royalties or other consideration . . . almost never harm[] competition"). Yet even in this ordinary circumstance, the patentee has provided consideration: the release of the defendant from a greater potential liability. From an economic perspective, releasing a party from potential liability is

as much consideration or a "payment" as is cash. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003) ("in the traditional context, implicit consideration flows from the patent holder to the alleged infringer"); Brett Dickey et al., *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 Annals Health L. 367, 389 (2010) ("the patent holder pays the infringer to settle the lawsuit by accepting lower damages"); Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 Antitrust L.J. 1033, 1033 (2004) ("the patent holder 'pays' to settle by accepting less in damages from the infringer than it expects to get from litigating"); *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J., by designation) ("*any* settlement agreement can be characterized as involving 'compensation' to the defendant who would not settle unless he had something to show for the settlement").

Hatch-Waxman settlements often have a different appearance for the simple reason that the Hatch-Waxman statutory framework encourages patent litigation before any allegedly infringing products have been sold, and thus before there is any potential damages award for the patentee to compromise. But Hatch-Waxman settlements are *economically* no different from traditional patent settlements. In each context, the economic substance of the settlement is that the plaintiff is providing consideration to the defendant in exchange for the defendant's agreement not to market its allegedly infringing product for a portion of the patent term. *See* Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles*, 15 Fed. Cir.

B.J. 617, 621 (2006) (Hatch-Waxman "creates a context in which payments from the patent owner to the infringer become explicit," but "does not change the underlying nature of the payments or make them more anticompetitive").

Nonetheless, the FTC has for years urged Congress to prohibit such settlements in the context of pharmaceuticals. Ten times within the past decade, bills have been introduced to make "reverse-payment" Hatch-Waxman settlements either presumptively or *per se* illegal.[7] Not one of these bills has been enacted. While Congress would have the authority to enact legislation that engages in line-drawing or adopts industry-specific rules, the courts should not endorse an antitrust rule of decision based on an industry-specific distinction that is purely formalistic, especially in the face of Congress's repeated refusal to enact the distinction legislatively.

b. Another lynchpin of the FTC's argument is the claim that its analysis shows that settlements accompanied by "payments"—which the FTC defines to include business deals in which any amount of money or other consideration flows from the patent holder to the generic company—result in a later license date for the generic drug than settlements without "payments." Pet. 20. The FTC's analysis, however, simply assumes its conclusion, by taking it

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[7] *See* S. 27, 112th Cong. (2011) (presumption of unlawfulness); S. 3677, 111th Cong. § 746 (2010) (same); S. 369, 111th Cong. (2009) (same); H.R. 3995, 112th Cong. (2012) (rule of *per se* unlawfulness); H.R. 3962, 111th Cong. § 2573 (2009) (same); H.R. 1706, 111th Cong. (2009) (same); H.R. 1902, 110th Cong. (2007) (same); H.R. 1432, 110th Cong. (2007) (same); S. 316, 110th Cong. (2007) (same); S. 3582, 109th Cong. (2006) (same).

as given that the cases that settled with payments would have settled without those payments.

There is no basis for that assumption. It is a fundamental tenet of dispute resolution that disputes often will not be resolved at all if the parties can negotiate only by compromising on a single term, such as the date on which a product will be marketed. When parties "negotiat[e] along a single dimension" and are prohibited from introducing other sources of value into the negotiation, there may be "no way to split the pie that leaves both parties satisfied." Roger Fisher et al., *Getting to Yes* 58 (3d ed. 2011). This dynamic is at least as true in Hatch-Waxman litigation as in any other context. Bernard & Tom, *supra*, at 630 (noting that "asymmetric time horizons" and "asymmetric expectations about litigation success can make it impossible to settle within the cashless, patent-term-splitting paradigm").[8] Settlement by negotiating along one dimension is possible only if the parties share a view of what is likely to

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[8] The *K-Dur* respondents challenge this proposition by citing their proffered expert's opinion that Schering and Upsher *could* have settled their patent case without a "reverse payment." BIO at 14, *Merck & Co. v. La. Wholesale Drug Co.*, No. 12-245 (filed Nov. 7, 2012). That opinion was based on the assumption that Upsher had, and that both Schering and Upsher *agreed* Upsher had, a 90% chance of winning. Making predictions only about what *could* have happened, and doing so based on supposedly precise soothsaying about the likelihood of a particular litigation outcome, however, is a "discipline [that] itself lacks reliability," *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 151 (1999), and thus is not a "fact" that could be appropriately relied upon in determining the relevant legal standard for evaluating Hatch-Waxman settlements. Moreover, that this purported evidence is contained in the *K-Dur* record does not make *K-Dur* a better vehicle for resolving the present circuit split.

happen if the case is pursued to judgment and place the same value on that outcome. Without other sources of value, there may be no way to "bridge th[e] gap" between the parties' irreconcilable bargaining positions. *Id.*[9]

c. In limiting parties in Hatch-Waxman patent litigation to negotiating only a licensed entry date, the FTC's proposed rule and the *K-Dur* holding would lead to fewer settlements of Hatch-Waxman cases. The deleterious consequences would be substantial.

First, public and private resources would be wasted. The courts have long favored private settlements of disputes. *McDermott, Inc. v. AmClyde*, 511 U.S. 202, 215 (1994) ("public policy wisely encourages settlements"); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1076 (11th Cir. 2005) (noting the "public problems associated with overcrowded court dockets, and the correlative public and private benefits of settlements"). Paragraph IV filers should not be conscripted as "unwilling private attorneys general." *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 532 (E.D.N.Y. 2005) (internal quotation marks omitted). The resources that would be consumed by unnecessarily protracted lawsuits are better used in productive endeavors: innovator companies' investing in research and development of new products, generic companies' bringing

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[9] The conclusions the FTC draws from its statistics are misleading for other reasons as well. For instance, the FTC measures "delay" in absolute terms—number of months from the settlement—without regard for the remaining length of the patent. When all else is equal, however, a patent with a longer term creates more litigation risk and thus more pressure to settle, including on terms that involve a "reverse payment" if needed to bridge the gap between the parties' positions.

other low-cost generics to market, and the courts' resolving disputes between parties who genuinely cannot do so themselves.

Second, the FTC's and Third Circuit's approach would reduce innovation. As a result of prolonged litigation and the inherent unpredictability of adjudication, the costs and uncertainty of patent enforcement would increase. For innovator companies, the increased cost and uncertainty surrounding pharmaceutical patent enforcement would in turn reduce the value of patents, which provide critical incentives for innovation. *See In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 203 (2d Cir. 2006) ("restricting patent settlements" would "heighten the uncertainty surrounding patents and might delay innovation"); *Valley Drug*, 344 F.3d at 1308 ("restricting settlement options, which would effectively increase the cost of patent enforcement," would "impair the incentives for disclosure and innovation"); Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 Tex. L. Rev. 503, 512-13 (2009) ("patents appear to be a prerequisite for the vast majority of pharmaceutical innovation").

Investment in the future development of new life-saving and life-enhancing medicines that strong patent protection fuels is critically important to consumer welfare. In rejecting the FTC's proposed rule, Congress declined to find that such future investment is less important than quickly decreasing the price levels of some of the current stock of patent-protected drugs. The courts should not impose a contrary judgment in the guise of interpreting the antitrust laws. As Judge Easterbrook has explained regarding the importance of maintaining incentives for innovation: "An antitrust policy that reduced

prices by 5 percent today at the expense of reducing by 1 percent the annual rate at which innovation lowers the costs of production would be a calamity. In the long run a continuous rate of change, compounded, swamps static losses." Frank H. Easterbrook, *Ignorance and Antitrust*, *in* Antitrust, Innovation, and Competitiveness 119, 122-23 (Thomas M. Jorde & David J. Teece eds., 1992). The FTC's and Third Circuit's analyses focus exclusively on short-term static prices, ignoring completely the long-range effect on innovation. Such an analysis is at odds with overall consumer welfare and, therefore, is an inappropriate basis for antitrust liability. *Reiter v. Sonotone Corp.*, 442 U.S. 330, 343 (1979) ("Congress designed the Sherman Act as a 'consumer welfare prescription.'").

Third, the FTC's and Third Circuit's approach would likely *reduce* generic competition for pharmaceuticals. A rule that drives up the cost and uncertainty of patent litigation would drive up cost and uncertainty not just for innovator pharmaceutical companies, but also for generic pharmaceutical manufacturers. This in turn would reduce generic manufacturers' incentive to challenge patents by making paragraph IV certifications in the first instance. *Asahi*, 289 F. Supp. 2d at 994 ("A ban on reverse-payment settlements would reduce the incentive to challenge patents . . . and so might well be thought anticompetitive."). As a result, the rate at which generic drugs are brought to market could well slow under the Third Circuit's rule—directly contrary to the FTC's stated objective of lowering the cost of pharmaceuticals. *See* Br. for Generic Pharm. Ass'n at 4, *Upsher-Smith Labs. Inc. v. La. Wholesale Drug Co.*, No. 12-265 (filed Oct. 1, 2012) ("Legal rules that limit the ability to settle drive up the cost of

patent challenges, meaning that fewer generic drug applications that would trigger a patent challenge will be filed."). That is why not just the brand-name pharmaceutical industry, but also the generic drug industry has uniformly opposed this rule and any rule like it.

Ultimately, the point is not that the magnitude of the pernicious expected effects of the FTC's and Third Circuit's approach can be easily measured and weighed, but that the FTC and the Third Circuit have made no effort to account for those effects. The FTC and the Third Circuit characterize their approach as application of "quick look" antitrust scrutiny. But "quick look" scrutiny is justified only when the "experience of the market" has shown that the conduct at issue has an anticompetitive tendency "so clear" that antitrust condemnation is warranted without full analysis. *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 779-81 (1999). Here, there is no such experience of the market, just the overly simplistic insistence by the FTC and the Third Circuit that consumers will benefit from outlawing dozens of settlements of Hatch-Waxman patent cases.

d. The FTC's and the Third Circuit's rule also would be unworkable. Under that rule, the settling parties can supposedly rebut the presumptive unlawfulness of a "reverse-payment" settlement by showing that the "reverse payment" did not result in "delayed entry." *K-Dur*, 686 F.3d at 218 (the presumption "could be rebutted by showing that the payment . . . was for a purpose other than delayed entry"). But neither the FTC nor the Third Circuit discusses the baseline from which a "delay" should be measured. It is far from obvious that there would have been earlier entry in the "but for" world in

which no settlement "payment" had been made. It may be that there would have been no settlement at all absent an accompanying business deal, in which case determining whether the settlement delayed generic competition would require determining the outcome of the underlying patent case if it had been litigated to judgment. If the innovator drug company would have prevailed, there would not have been any delay because the generic drug would not have entered the market until the expiration of the patent.

But even if the FTC were correct that every patent case that has been or would be settled with a "reverse payment" could and would alternatively be settled without a "reverse payment," the licensed entry date under the latter hypothetical settlement could be determined only by evaluating the likelihood of success of the patent case, as the FTC appears to acknowledge. Pet. 22-23 (settlement is "likely to reflect the parties' assessment of their respective prospects of success in the infringement suit"). This in turn would be a truly Herculean task, more difficult even than determining what the final judgment in the patent case would have been absent a settlement.

To be sure, *K-Dur* proclaimed that "there is no need to consider the merits of the underlying patent suit." *K-Dur*, 686 F.3d at 218. But that comment was part of the court's discussion of whether the presumption of unlawfulness should apply in a particular instance, not whether and how such a presumption—if applied—can be rebutted. Notably, the United States has agreed that analysis of "reverse-payment" settlements ultimately would involve retrospectively predicting what the outcome in the patent case would have been had it proceeded to judgment. *See* Pet. 21 n.6 (acknowledging that the

United States has argued to this Court in three previous briefs that "the antitrust inquiry should include an assessment of the likelihood that the brand-name manufacturer would have prevailed in the underlying infringement suit").[10] Several commentators have advanced this view as well.[11] It is hard to see how causation or damages in an antitrust challenge to a patent settlement could be resolved without essentially re-litigating the merits of the underlying patent case to evaluate the "but for" world.

Requiring trial courts, juries, and settling parties to engage in this exercise would be untenable. This Court has observed that "[i]t is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case.' *Whitmore v. Arkansas*, 495 U.S. 149, 159-60 (1990). This is particularly true in patent cases, which are

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[10] *See also* U.S. Br. at 12, *Joblove v. Barr Labs., Inc.*, 551 U.S. 1144 (2007) (No. 06-830) (filed May 23, 2007) ("In determining whether the exclusionary effect of a settlement involving a reverse payment renders the settlement unreasonable and anticompetitive, a court at a minimum should take into account the relative likelihood of success of the parties' claims, viewed ex ante."); U.S. Br. at 11, *Schering*, *supra* note 5 ("[A]n appropriate legal standard should take into account the relative likelihood of success of the parties' claims, viewed *ex ante*.").

[11] *See, e.g.*, Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1759 (2003) (arguing that the "infringement plaintiff can defend [against the presumption of unlawfulness] by showing" that "the ex ante likelihood of prevailing in its infringement lawsuit is significant"); Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 Mich. L. Rev. 37, 41 (2009) ("If the parties can demonstrate that the payments represent a reasonable assessment of litigation success, then they can rebut this presumption.").

notoriously unpredictable.[12] The task would be further complicated because the antitrust evaluation of patent litigation might be reviewed by the regional circuits. *See Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 807-09 (1988). The resulting state of affairs would have the regional circuits attempting to discern the "likelihood" of how the Federal Circuit would have decided the hypothetical appeal from the hypothetical judgment in the settled patent case.

Brand-name and generic pharmaceutical companies, like most litigants, settle to avoid the uncertainty of adjudication. *Hertz Corp. v. Friend*, 130 S. Ct. 1181, 1193 (2010) ("Predictability is valuable to corporations making business and investment decisions."); *Carson v. Am. Brands, Inc.*, 450 U.S. 79, 87 (1981) ("Settlement agreements may thus be predicated on an express or implied condition that the parties would, by their agreement, be able to avoid the costs and uncertainties of litigation."). The legality of their efforts in doing so should not be subject to the magnified uncertainty of how a judge or jury, years later, handicap how a different judge, jury, and the Federal Circuit would have resolved the supposedly settled case.

e. If allowed to stand, *K-Dur* would also wreak years of litigation over what constitutes a "reverse payment." The *K-Dur* court referred in passing to "*money* that changed hands" in connection with a

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[12] *See* U.S. Court of Appeals for the Fed. Circuit, *Affirmance and Reversal Rates for District Court Patent Infringement Appeals*, www.patentlyo.com/files/caseload_patent_infringement_affirmance_and_reversal_rates_2001-2010.pdf (showing that over 40% of patent appeals result in reversal or vacatur at least in part).

settlement, 686 F.3d at 218 (emphasis added), but otherwise did not define "reverse payment." The FTC has made clear that it views a "reverse payment" as anything of "economic value" that an innovator provides a generic—a concept far broader than payment of money. *See* FTC Pet. for Reh'g En Banc at 13, *Watson*, 677 F.3d 1298 (No. 10-12729-DD) (filed June 11, 2012) ("[The] burden-shifting approach should apply whenever the patent holder provides economic value to the challenger in any form in connection with delayed entry."); FTC Br. at 24 n.26, *K-Dur*, 686 F.3d 197 (No. 10-2077) (filed May 18, 2011) ("The rule we urge should apply whenever the patent holder provides economic value to the challenger in any form.").

Disputes over the definition of "reverse payment" have already arisen in district courts within the Third Circuit. When an innovator company and a generic company settle Hatch-Waxman litigation by agreeing on a future date for licensed generic entry, the innovator company sometimes agrees that the innovator will not itself launch an "authorized generic" for some period of time after the agreed-upon entry date.[13] An agreement of this form is essentially a time-limited exclusive license and does not involve any exchange of money. Yet the FTC has repeatedly advanced the view that such an agreement, when

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[13] An authorized generic is a drug manufactured in accordance with the innovator's own FDA approval but sold, by either the innovator or a licensee, using a different product name and at a reduced price. John M. Rebman, *Dr. Strange Drug, Or: How I Learned to Stop Worrying and Love Authorized Generics*, 12 DePaul J. Health Care L. 159, 159 (2009). Introducing an authorized generic allows an innovator to capture a portion of the market for generic drugs rather than cede it to generic manufacturers. *Id.* at 168.

contained in a settlement of Hatch-Waxman patent litigation, is a "reverse payment" because the innovator's promise not to authorize a generic constitutes "economic value." *See, e.g.*, FTC Br. at 6-12, *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 12-cv-995 (D.N.J.) (filed Oct. 5, 2012); FTC Br. at 5-11, *In re Effexor XR Antitrust Litig.*, No. 11-cv-5479 (D.N.J.) (filed Aug. 10, 2012). If a cashless promise that maintains the 180-day exclusivity promised to generics under Hatch-Waxman can be a forbidden "reverse payment," it is difficult to see any limiting principle for the FTC's proposed rule.

C. The Court Should Grant The FTC's Petition

1. This case is a better vehicle than *K-Dur*

Solvay agrees with the FTC that this case is a better vehicle for resolving the circuit split than is the *K-Dur* case (Nos. 12-245 and 12-265).

a. This case is a better vehicle than the *K-Dur* case because it arises from a final dismissal with a simple record, whereas *K-Dur* reaches this Court in an interlocutory posture from reversal of a grant of summary judgment on a fact-intensive record. In *K-Dur*, the court of appeals remanded for further proceedings under the new standard it announced. If the case proceeds on remand, there are many ways in which the case could be resolved that would render the choice of legal standard irrelevant.

For example, the parties in *K-Dur* dispute whether the innovator company, Schering, made any payments to the generic in exchange for the agreed-upon date of generic entry when it bought licenses from Upsher (one of the ANDA filers) for unrelated drugs.

K-Dur, 686 F.3d at 205. The antitrust defendants in *K-Dur* argue that the licenses were priced at fair market value, and thus there was no "reverse payment." *See* BIO at 10, *Merck*, *supra* note 8. The Third Circuit did not address this issue, but the Eleventh Circuit, in evaluating the same settlement, found the "payments [were] a fair price" for the licenses and that Schering had "made a stand-alone determination that it was getting as much in return from these products as it was paying." *Schering*, 402 F.3d at 1071. If the licenses are found on remand to reflect fair value, then the settlement would not include a "reverse payment," or, put another way, the only payments would have been for "a purpose other than delayed entry" and thus not anticompetitive even under the Third Circuit's test. *See K-Dur*, 686 F.3d at 218.

Similarly, *K-Dur* involves disputes about the strength of the antitrust defendants' positions in the underlying Hatch-Waxman patent litigation. *See In re K-Dur Antitrust Litig.*, 2009 WL 508869, at *29 (D.N.J. Feb. 6, 2009). If it were found on remand that, in the absence of a settlement, Schering would have won the patent litigation and kept the generics off the market, then the settlement could not have delayed generic entry. This would mean that the settlement caused no injury to the antitrust plaintiffs, so their case would fail even under the Third Circuit's test.

When, as in *K-Dur*, the interlocutory posture of a case means the question presented in a petition may "become quite unimportant by reason of the final result, or of intervening matters," the Court has held that it "should not issue a writ of certiorari . . . unless it is necessary to prevent extraordinary

inconvenience." *Am. Constr. Co. v. Jacksonville, Tampa & Key West Ry. Co.*, 148 U.S. 372, 384 (1893); *see also Bhd. of Locomotive Firemen & Enginemen v. Bangor & Aroostook R.R. Co.*, 389 U.S. 327, 328 (1967) (per curiam) ("[B]ecause the Court of Appeals remanded the case, it is not yet ripe for review by this Court."). In contrast to *K-Dur*, in which the question presented could be made irrelevant by proceedings on remand regardless of whether this Court grants certiorari to resolve the current circuit split, this case arises from a complete dismissal, so there will be no further proceedings unless this Court grants certiorari.

b. The underlying patent litigation in this case included disputes over patent validity and infringement, whereas the underlying patent litigation in *K-Dur* involved only disputes over infringement. Solvay does not believe it should matter to the antitrust analysis of a patent settlement whether validity or infringement or both were contested in the settled litigation. But the antitrust plaintiffs in *K-Dur* have urged the courts to adopt an antitrust analysis that distinguishes between validity and infringement defenses in the underlying patent litigation—on the ground that a patent is presumed valid but there is no similar presumption of infringement. *See* Appellants' Opening Br. at 35-38, *K-Dur*, 686 F.3d 197 (No. 10-2077) (filed May 11, 2011). Granting certiorari in this case would enable the Court to consider cases in which the generic manufacturer challenges the validity of the patent as well as those in which the generic manufacturer contests infringement.

2. Alternatively, the Court should grant the petitions in *K-Dur* along with the petition in this case

In the alternative, as the FTC also suggests (Pet. 29, 32-33), the Court could grant the petitions for writs of certiorari in this case as well as in *K-Dur*.

a. Granting certiorari in both cases would allow the Court to consider a greater variety of business arrangements when considering whether—and if so, how—business arrangements entered at the time of a patent litigation settlement are relevant to the antitrust analysis.

As discussed above, the Third Circuit's presumption of illegality is not as clear as the Third Circuit and FTC have portrayed it. The concepts of what constitutes a "reverse payment" and how the presumption can be rebutted are unclear under the Third Circuit's test. Having examples of several different types of business deals—including for co-promotion and back-up manufacturing in this case, and for licenses to unrelated products in *K-Dur*—could be helpful in considering the implications of that test.

b. That the FTC seeks only prospective relief in this case and the *K-Dur* plaintiffs seek only damages is also a reason why the Court may wish to grant certiorari in both cases. Doing so would allow the Court to consider the difficulty of applying the Third Circuit's test to both kinds of claims for relief. In the FTC's view, the fact that the FTC seeks only prospective relief means that, by granting certiorari in only this case, the Court could avoid considering "whatever uncertainties may arise in fixing the damages caused by a reverse-payment agreement." Pet.

31. But whether the potential legal tests would create unmanageable uncertainties with respect to causation and damages is important to consider. As explained above, one serious problem with the Third Circuit's test is that, to determine what damages (if any) are owed, the parties would have to re-litigate the underlying patent suit to determine when generic entry would have occurred absent the settlement. *See supra* pp. 24-27.

Contrary to the FTC's suggestion, the Third Circuit's test faces essentially the same uncertainties in a case, like this one, in which the plaintiff seeks only prospective relief. Rebutting the Third Circuit's presumption would involve determining whether a settlement in fact delayed generic entry, which in turn would involve determining when the generic product would have entered the market absent the settlement. And resolving that question would require relitigating the underlying patent case to determine the likelihood that the generic product would have been found to infringe. This need to re-litigate patent cases follows from the Third Circuit's rule, not from the form of relief sought. Granting certiorari in this case and in *K-Dur* would permit the Court to consider the Third Circuit's test, and the need to relitigate the underlying patent case resulting from that test, in the context of claims for damages and injunctive relief.

CONCLUSION

The petition for a writ of certiorari should be granted.

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November 13, 2012

RESPONDENT'S BRIEF

No. 12-416

IN THE
Supreme Court of the United States

FEDERAL TRADE COMMISSION,
Petitioner,
v.
ACTAVIS, INC., ET AL.,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF FOR RESPONDENT SOLVAY PHARMACEUTICALS, INC.

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QUESTION PRESENTED

Whether the settlement of bona fide Hatch-Waxman patent litigation in which the accused generic infringer is licensed to come to market before the expiration of the innovator drug company's patent and which does not exceed the exclusionary potential of the patent is rendered presumptively illegal merely because it also includes a business deal that is alleged to provide additional value to the accused infringer.

RULE 29.6 STATEMENT

The corporate disclosure statement included in the brief filed at the certiorari stage is amended as follows:

Respondent Solvay Pharmaceuticals, Inc., now known as AbbVie Products LLC, is a wholly owned subsidiary of AbbVie Inc. and is no longer a wholly owned subsidiary of Abbott Laboratories. AbbVie Inc. is a publicly traded company, and no person beneficially owns 10% or more of its outstanding shares.

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INTRODUCTION

For a century, this Court has analyzed antitrust challenges to patent-related restraints by evaluating whether the restraint exceeds the scope of the patent. The FTC now asks the Court to abandon that precedent in favor of a new, untested rule focusing on the existence of a so-called "reverse payment" in pharmaceutical settlements arising from patent litigation under the Hatch-Waxman Act. Although the FTC characterizes its new rule as a "quick-look" analysis, its brief makes clear that the test amounts to a rule of *per se* illegality. Either way, the rule is unwarranted. *Per se* or quick-look treatment under the antitrust laws would be available only if long judicial experience or persuasive evidence showed "reverse-payment" settlements to be almost always anticompetitive. There is no such long judicial experience, and the FTC has no persuasive evidence that reverse payments delay generic entry or protect "weak" patents. In fact, there is substantial reason to believe the opposite.

Perhaps because its new rule finds no support in this Court's precedents, the FTC primarily invokes policy arguments. But policy considerations weigh heavily against the FTC's rule, which would be hopelessly unmanageable for courts and litigants alike. The FTC admits that a rule that would require relitigating the underlying patent case in any antitrust action it brought would be unworkable—but then concedes that this task may be necessary in private cases, which far outnumber FTC enforcement actions. In addition, because the concept of a "reverse payment" lacks any principled limitations, the FTC's rule would render suspect a wide swath of patent settlements far beyond the Hatch-Waxman context.

Finally, to the extent Hatch-Waxman has created any undesirable policies, the solution is for Congress—and not the courts—to weigh costs against benefits and formulate any potential industry-specific rules.

STATEMENT OF THE CASE

A. Statutory Background

Until 1984, a company seeking to market a generic drug needed to submit a New Drug Application (NDA) that included safety and efficacy data specific to its generic version of the drug. If a patent covered the drug, the generic company's development effort would usually infringe the patentee's legal monopoly on "making" and "using" the drug. *See Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 861 (Fed. Cir. 1984). As a result, the generic development work generally could not begin until patent expiration.

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly known as the Hatch-Waxman Act. Under Hatch-Waxman, a generic drug company can obtain FDA approval by filing an Abbreviated New Drug Application (ANDA), which relies on the brand-name (or "innovator") drug's clinical trial data to establish safety and efficacy. The generic company need show only that its proposed generic has the same active ingredient as and is bioequivalent to the innovator's drug. 21 U.S.C. § 355(j)(2)(A); *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2574 (2011).[1] The Act also

[1] Unless otherwise specified, citations of the United States Code refer to the 2000 edition in effect during the events relevant to this case. *See* FTC Br. 2 n.1.

abrogates the innovator drug company's traditional patent right to preclude the "making" and "using" of its patented drug in a generic company's efforts to develop a copy of that drug. 35 U.S.C. § 271(e)(1). Generic drug companies can now copy drugs much more quickly and cheaply and can do so before patent expiration. In addition, Hatch-Waxman allows generic companies to file a "paragraph IV" certification when they contend the patent covering the drug is invalid or not infringed, and creates a framework for litigation of resulting patent disputes. This framework is described in detail in the FTC's brief and the decision below. FTC Br. 4-6; Pet. App. 6a-9a.

Congress again legislated in this area when it passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. No. 108-173, 117 Stat. 2066. Under the MMA, agreements settling Hatch-Waxman litigation must be submitted to the FTC and the Department of Justice. *Id.* § 1112, 117 Stat. at 2461-62 (codified as amended at 21 U.S.C. § 355 note (2006)). Nothing in the MMA substantively regulates such agreements.

B. Factual Background

1. The AndroGel invention

In 1995, Unimed Pharmaceuticals, Inc., now a subsidiary of respondent Solvay Pharmaceuticals, Inc., began collaborating with Besins Healthcare, S.A. to develop a new drug for treating men with chronically low testosterone. After years of clinical trials, Unimed and Besins determined that their drug, AndroGel, was safe and effective. Unimed began selling AndroGel in 2000. JA 36-37, ¶¶ 31-33.

AndroGel represented a significant advance over previously approved testosterone formulations, which were mostly delivered by injections or skin patches. It met the need for a convenient dosage form that produces a steady level of testosterone in the bloodstream.

Unimed and Besins applied for a patent on AndroGel, disclosing the formulation to the public. The U.S. Patent and Trademark Office granted the application as U.S. Patent No. 6,503,894 ('894 patent) in January 2003. The patent will expire in 2020. JA 38-39, ¶¶ 39-43. AndroGel has since become a medical and commercial success, improving the lives of millions of patients.

2. Applications for generic versions of AndroGel and ensuing litigation

In May 2003, Watson Pharmaceuticals, Inc. (now Actavis, Inc.) and Paddock Laboratories, Inc. each filed an ANDA seeking approval for a generic version of AndroGel that contained a paragraph IV certification against the '894 patent. Unimed and Besins promptly filed Hatch-Waxman patent-infringement lawsuits against Watson and Paddock. JA 39-40, ¶¶ 44, 47.

The parties litigated the cases for three years, produced hundreds of thousands of pages of documents, took nearly 40 depositions, and retained numerous scientific experts. Pet. App. 33a. Paddock ultimately sought litigation funding from a larger generic drug company, Par Pharmaceutical Companies, Inc., which received the exclusive right to distribute Paddock's generic version of AndroGel if

and when the product could come to market. JA 40, ¶ 46.

The '894 patent was specifically intended to cover AndroGel and disclosed AndroGel's composition. Neither Watson nor Paddock disputed that its proposed generic product used the same ingredients as AndroGel in very nearly the same amounts. But each defendant raised numerous defenses, including that the patent did not cover AndroGel because of an alleged technical error in claim drafting and that the patent was invalid. They filed partial summary judgment motions, but those motions addressed only some of the patent claims and could not have defeated Unimed's entire suit.

The district court has since held, in the context of antitrust class actions filed by private plaintiffs, that Unimed had an objectively reasonable expectation of success in the patent litigation. *In re AndroGel Antitrust Litig. (No. II)*, — F. Supp. 2d —, 2012 WL 5352986 (N.D. Ga. Oct. 30, 2012), *appeal docketed*, No. 12-15562-BB (11th Cir. Oct. 30, 2012). Although Watson received final approval for its product in January 2006, it chose not to come to market and risk facing damages liability if it lost the patent case. JA 46, ¶ 65.

In September 2006, before the district court decided any substantive motions, the parties settled. In separately negotiated agreements, Solvay (Unimed's parent company) agreed to license Watson and Paddock to launch their respective generic versions of AndroGel in August 2015—five years before the '894 patent will expire. JA 46, 49, ¶¶ 65, 76. In exchange, each generic company agreed to respect the patent by not marketing its generic drug before August 2015. Watson, Paddock, and Par also agreed

to provide services to Solvay before 2015—Watson to promote AndroGel to urologists, Paddock to provide manufacturing capacity for the drug, and Par to promote it to primary care physicians—and Solvay agreed to pay for those services. JA 46, 48, ¶¶ 66, 74. There has been no allegation that any party did not provide its agreed-upon services or that those services were not valuable, though the FTC alleges that Solvay overpaid for them.[2] Solvay's payments represented less than 10% of AndroGel's revenues at the time. *See* JA 28, ¶ 2.

C. Proceedings Below

1. The FTC investigated the settlements for two years and then filed this case. Shortly thereafter, several private plaintiffs brought follow-on putative class actions.

In its operative complaint, the FTC did not allege that the '894 patent was fraudulently procured, that Unimed's patent suits were "sham" litigation, or that the settlements constituted patent misuse. It alleged

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[2] The FTC makes the further allegations that: (1) an internal Solvay document shows that Solvay believed it would need to make payments to Watson and Par/Paddock to induce their agreement to a 2015 entry date; and (2) Watson knew Solvay planned to introduce a new AndroGel formulation by 2015, and this would decrease the value of generic AndroGel. FTC Br. 11; JA 45, ¶¶ 62-63. Even if true, these allegations would show at most that the business deals were necessary to bridge the gap between the entry dates to which the parties respectively would have been willing to agree. *See infra* § IV.C (explaining that the FTC's test would prevent many cases from settling). Moreover, the allegation about a new formulation concerns only the settlement between Solvay and Watson; it has no bearing on the settlement among Solvay and Par and Paddock.

only that Solvay's business agreements with Watson, Par, and Paddock were not "independent business transactions," that Solvay overpaid for the services, and that the agreements induced Watson, Par, and Paddock to accept a later entry date for their generic versions of AndroGel. JA 50-53, ¶¶ 81-85. The complaint also alleged that Unimed was "not likely to prevail" in its lawsuits against Watson and Paddock. JA 53, ¶ 86.

2. The district court dismissed the complaint, rejecting the FTC's theory that "it should be presumptively unlawful for companies to settle a patent dispute with reverse payments." Pet. App. 51a. It observed that the only alleged "exclusion" ended five years before the close of the '894 patent's term. *Id.* at 48a-49a. The alleged exclusion was therefore within the lawful "environment of exclusion" of the patent. *Id.* at 48a (quotation marks omitted).

Additionally, the district court dismissed the private plaintiffs' claims concerning the settlements. *Id.* at 47a-52a. It has since granted summary judgments to respondents on the private plaintiffs' further claims (not asserted by the FTC) that Unimed's patent litigation was a sham. *AndroGel*, 2012 WL 5352986. Appeals from that judgment are stayed.

3. The Eleventh Circuit affirmed. It observed that the usual antitrust rules prohibiting agreements not to compete or divide markets do not apply in the patent context because a patent is "a lawful right to exclude others from the market." Pet. App. 17a (quotation marks omitted). The court held that there cannot be antitrust liability for an "exclusionary" effect that is within the bona fide exclusionary potential of the patent. *See id.*

The court of appeals rejected the FTC's proposal that antitrust liability turn on relitigating the merits of the patent case to determine whether Solvay was "likely to prevail." *Id.* at 30a. This "retrospective predict-the-likely-outcome-that-never-came" inquiry would be unmanageable, requiring courts to undertake the "turducken task" of "attempt[ing] to decide how some other court in some other case at some other time was likely to have resolved some other claim if it had been pursued to [a] judgment" that was never rendered. *Id.* at 33a, 36a. The court expressed that this "retrospective" approach was "unlikely to be reliable," would be burdensome for the parties and the court, would "undo much of the benefit of settling," and would "discourage settlements." *Id.* at 33a.[3]

4. After the court of appeals denied the FTC's petition for rehearing en banc, Pet. App. 62a, this Court granted certiorari.

SUMMARY OF THE ARGUMENT

I. The FTC argues that the scope-of-the-patent rule is flawed because it presumes validity and infringement when considering antitrust challenges to patent settlements. But more than a century of this Court's precedents have taken that approach.

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[3] As Par and Paddock argue, their settlement is immune from liability for two independent reasons regardless of the outcome of this appeal: (1) the district court's consent injunction that currently restrains Par and Paddock's generic entry provides *Noerr-Pennington* immunity; and (2) when Par and Paddock entered into their settlement, they believed that, as pre-MMA second filers, they could not have obtained an earlier agreed-upon entry date even absent any alleged payment. The court of appeals did not reach either of these arguments.

Only if a restraint falls outside the scope of a patent, or the patent was obtained through fraud or asserted in a sham manner, is there a basis for antitrust scrutiny. The Court has expressly refused to discount the patent's exclusionary scope because of the possibility that the patent someday might be found invalid or not infringed.

Like every previous federal-court decision confronting an antitrust challenge to this kind of Hatch-Waxman settlement, the Eleventh Circuit properly applied these precedents and considered whether the terms of the settlements here fell within the scope of the patent at issue. The court upheld the settlements as lawful because the FTC did not allege that Solvay's patent claims were sham or that the patent was fraudulently obtained; and, as the FTC admits, the settlements here provide for generic competition in 2015, five years earlier than the result if Solvay had prevailed in the litigation.

II. The FTC seeks to jettison the established scope-of-the-patent analysis. It urges the Court to adopt a new, untested antitrust rule that turns on whether a settlement includes a so-called "reverse payment" from the patentee to the accused infringer, and treats every settlement featuring such a "payment" as presumptively illegal under the antitrust laws. Only one federal court has embraced this standard, and only within the last eight months.

Although the FTC describes its novel rule as a "quick-look" analysis, the rule would function as a *per se* prohibition of "reverse-payment" settlements, because no "rebuttal" to the presumption of anticompetitive effect is realistically possible under the FTC's test. *Per se* condemnation is appropriate only after "courts have had considerable experience"

with a category of restraint and that experience demonstrates that the restraint is almost always anticompetitive. *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 886 (2007). Here, there is no such judicial experience. "Quick-look" analysis has been applied only to arrangements that resemble practices that are *per se* illegal, and for which the "anticompetitive effects can easily be ascertained." *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 770-71 (1999). But there is no resemblance between the patent restraint at issue in this case and any practice that is *per se* illegal, and it is far from obvious that "reverse-payment" settlements have anticompetitive effects.

At bottom, the FTC's argument ignores the existence of the patent. The FTC falsely analogizes to agreements by competitors to divide markets where no patents are involved—agreements that unquestionably harm competition and are *per se* illegal. But a patent represents a Congressional grant of the power to exclude. A settlement within the scope of a valid and infringed patent has no anticompetitive effect, regardless of any payments between the parties. Continuing to litigate instead of settling would keep the generic off the market for even longer if the patentee prevailed. This Court's precedents teach, moreover, that unless and until a patent is adjudicated invalid or not infringed, good-faith claims of validity and infringement must be assumed true for antitrust purposes.

The FTC responds by suggesting that pharmaceutical patents are generally "weak," and so should not be presumed valid or infringed for antitrust purposes. This argument is not only legally irrelevant, but also contrary to empirical data. A study

conducted by the FTC's own amici, for example, shows that pharmaceutical patents have been held valid in nearly three-quarters of cases litigated to judgment.

While the FTC's position is predicated entirely on the assumption that "reverse-payment" settlements cause later generic entry dates, the FTC has not come close to supporting this assumption. It relies primarily on its characterization of a non-public FTC analysis. Even setting aside that its study has not been subjected to public scrutiny, it does not show that reverse payments cause later entry dates. More importantly, the FTC ignores the risk that any short-term benefit of its rule would be swamped by a decrease in long-term consumer welfare from weakening the incentives for pharmaceutical innovation.

III. The FTC's rule also would be unworkable. *First*, the FTC concedes that any standard that requires relitigating the underlying patent dispute would be unmanageable and would create a "powerful disincentive to settlement." FTC Br. 54. Yet the FTC also concedes that its rule would require relitigating the underlying patent dispute in private antitrust lawsuits, which constitute most of the challenges to Hatch-Waxman settlements. Moreover, under a true "quick-look" (or rule-of-reason) analysis, relitigation of the patent case would occur even in FTC actions because a patent settlement has no anti-competitive effect if the patent is valid and infringed.

Second, the FTC's rule would render many non-Hatch-Waxman patent settlements presumptively illegal. The FTC does not define "reverse payment" in its brief here, but its public statements acknowledge that the concept necessarily would extend to many common settlement terms, and would not be limited

to a transfer of money. Indeed, a "payment" could extend even to a provision that does no more than release a settling party's damage claim.

Third, the "rebuttal" opportunity the FTC rule would permit is not the traditional one under the quick-look approach; the FTC would not permit rebuttal of the presumption of illegality by showing that a settlement is actually procompetitive. Instead the rebuttal would be limited to an ill-defined and unmanageable *five-factor test* that a court would need to consider to determine whether the "value" given to the generic was reasonable consideration for something other than a later entry date. Parties could spend years litigating this issue.

IV. The policy arguments invoked by the FTC are either factually unsupported, demonstrably incorrect, or inconclusive. They do not justify creating an untested new approach to antitrust law and patent settlements.

The scope-of-the-patent test, which has been the governing legal standard for a decade, has not harmed generic competition. Generic companies have aggressively challenged patents under this test. Although the FTC suggests that patentees might engage in seriatim "reverse-payment" settlements with would-be generic competitors, that scenario is economically infeasible and contrary to experience.

Neither do considerations of legislative history and statutory purpose support the FTC's rule. The Hatch-Waxman Act did not favor early generic entry at all costs, as the FTC and its amici suggest. To the contrary, the Act recognized the importance of strong patent rights to innovation: it *extended* many patent terms, while creating "the opportunity for competition in generic drugs to be on the market after

that patent has expired." 130 Cong. Rec. 24,430 (1984) (Rep. Waxman). When providing for litigation of disputes regarding patent validity and infringement, Congress did not intend to substantively modify the patent laws at all.

Ultimately, the FTC's test would have pernicious consequences for the courts and consumers. If settlement discussions are confined to the "single dimension" of splitting the patent term, differing expectations about a case's settlement value and differing resource constraints and business interests will frequently make settlement impossible. This would contravene the strong public policy in favor of settlement and undermine incentives for brand manufacturers to invent new drugs.

ARGUMENT

I. THE SCOPE-OF-THE-PATENT RULE CORRECTLY REFLECTS PATENT AND ANTITRUST PRECEDENTS

The court below, consistent with many other courts, concluded that patent settlements are subject to antitrust scrutiny only if (1) the patent was procured by fraud, (2) the assertion of the patent was a sham, or (3) the settlement's exclusionary restraint exceeds the exclusionary scope of the patent. Pet. App. 28a. The FTC complains that this scope-of-the-patent rule accepts the exclusionary scope of a duly issued patent even though the patent claim might not be upheld if the case were fully litigated. But the scope-of-the-patent test follows precisely the approach this Court's precedents take.

A. Only Restraints Outside The Scope Of A Patent Have Been Subjected To Antitrust Scrutiny

There is no dispute that "patent grants [are] an exception" to antitrust restrictions. *United States v. Line Material Co.*, 333 U.S. 287, 309 (1948). The antitrust analysis of patent-related restraints differs from that of other restraints because the purpose of patents is to enable patentees to exclude competition and charge supra-competitive prices for the life of the patent. *See* U.S. Const. art I, § 8, cl. 8. This Court has reconciled patentees' exclusionary rights with antitrust scrutiny in two ways.

First, antitrust law may be implicated where the patent was improperly acquired or asserted, *i.e.*, for fraud on the PTO or sham litigation. *See Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 178 (1965); *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 51 (1993) (*PRE*).

Second, the Court's precedents focus on whether patent-related restraints exceed the substantive or temporal scope of the patent, an idea arising both in antitrust cases and in the related doctrine of patent misuse. Restraints that exceed the patent's scope are subject to traditional antitrust analysis, such as *per se* condemnation or the rule of reason. A patentee may, for example, implicate the antitrust laws by using its patent to control the sale of unpatented products, *see Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 491 (1942), or to seek royalties beyond the patent term, *see Brulotte v. Thys Co.*, 379 U.S. 29, 33 (1964). Similarly, a patentee may implicate the antitrust laws by restricting the resale of patented products, *see United States v. Masonite Corp.*, 316

U.S. 265, 310-11 (1942), which is beyond the scope of a patent because the initial sale terminates all patent rights, *see Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617, 625 (2008). Antitrust law may apply also to patent pools, where multiple patentees jointly restrain trade beyond what a single patentee could achieve with its own patents. *See Line Material*, 333 U.S. at 288-89; *United States v. New Wrinkle, Inc.*, 342 U.S. 371, 376-79 (1952); *see also United States v. Singer Mfg. Co.*, 374 U.S. 174, 189 (1963) (patent pool used to implement concerted refusal to deal). Patent misuse is likewise evaluated with reference to the "physical or temporal scope of the patent." *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 343 (1971) (discussing *Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 666 (1944)).

The principle applied in each of these cases is the same: exclusionary effects are subject to antitrust scrutiny when they reach "beyond the limits of the patent monopoly," *i.e.*, the challenged restraint's exclusionary effect is greater than the patent potentially provides. *Line Material*, 333 U.S. at 308; *see also United States v. Gen. Elec. Co.*, 272 U.S. 476, 485 (1926) (antitrust laws implicated "only when" the patentee "steps out of the scope of his patent rights"); *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436, 456-57 (1940) (patentee may not "control conduct by the licensee not embraced in the patent monopoly"); 6 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 1427c, at 216-17 (3d ed. 2012) (Masonite "exceeded" the patent "privilege"). That the restraints exceed the scope of the patent can be demonstrated by showing that the restraint on competition is greater than what could have been achieved through litigation. *See, e.g.*,

United States v. Univis Lens Co., 316 U.S. 241, 250 (1942) (relying on fact that a "patentee cannot control the resale price of patented articles which he has sold . . . by resort to an infringement suit").

By contrast, this Court has not applied antitrust scrutiny or the patent misuse doctrine to restraints within the scope of a patent. For example, the Court has held that antitrust law does not prohibit a patentee from dividing the market for its invention through exclusive licenses with territorial or field-of-use restrictions, *see Gen. Talking Pictures Corp. v. W. Elec. Co.*, 304 U.S. 175, 179-81 (1938), even though, absent a patent, such vertical restraints are subject to antitrust scrutiny—at one time, *per se* condemnation, *see Cont'l T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 43 (1977) (replacing *per se* rule against non-price vertical restraints with rule of reason).

B. Antitrust Analysis Is Unaffected By The Possibility A Patent Could Be Held Invalid Or Not Infringed

In evaluating patent-related restraints under the antitrust laws, this Court has neither required adjudication of the underlying patent's scope nor validity or discounted the patent merely because it was challenged in litigation. Unless and until a patent claim is judicially rejected, antitrust law assumes its validity. *See Masonite*, 316 U.S. at 280 (antitrust courts are not "warranted in assuming, in absence of a definite adjudication, that one grant by the Patent Office is more valid than another").

In *Standard Oil Co. v. United States*, 283 U.S. 163 (1931), the Court's antitrust analysis of patent settlements treated the patents as valid and infringed, despite the expressly recognized contrary possibility.

There, four competing licensors of gasoline cracking technology had sued each other for patent infringement. Each claimed the others' patents were invalid and not infringed by its own technology. The parties settled by cross-licensing the patents and agreeing to share profits from licensing their technologies—with a fixed royalty price to their respective downstream licensee customers. *See id.* at 167-68.

The government contended that the licensors' agreements "constitute[d] an unlawful combination under [section 1 of] the Sherman Act." *Id.* at 171. This Court rejected that contention, holding that "[w]here there are legitimately conflicting [patent] claims or threatened interferences, a settlement by agreement, rather by litigation, is not precluded by the Act." *Id.*

The government had argued that the patents were invalid and not infringed, and that the patents' "infringement had been asserted merely as a means of" making the profit-pooling contracts seem legal. *Id.* at 180. Although it "confirmed the finding of presumptive validity," the district court had questioned whether the patents were actually infringed, ruling that each patent's claims "should be interpreted narrowly" and that "the respective inventions might be practiced without infringement of the adversely owned patents." *Id.* at 180-81. Nevertheless, the district court held that the infringement claims were "sufficient to justify the threats and fear of litigation," *i.e.*, had been asserted in "good faith." *Id.* at 180. Those findings were not appealed, so this Court accepted them for purposes of its analysis. *Id.* at 181. That analysis explained that the agreements to fix and share license royalties were within the rights granted by their patents. Critically, this was

true even though it appeared the patent-infringement claims may well have failed if litigated to conclusion.[4] In other words, this Court implicitly concluded that the antitrust analysis—which specifically found that the conduct was not anticompetitive because of the patents—did not require it to "consider any of the issues concerning the validity or scope of the cracking patents," because the patents had been asserted in "good faith." *Id.* at 181.

Likewise, *Dawson Chemical Co. v. Rohm & Haas Co.*, 448 U.S. 176 (1980), concerned whether a tying arrangement between a patented process and a non-staple good constituted patent misuse. Again, the Court analyzed the patent misuse issue without regard to the petitioners' "assert[ion of] the invalidity of Rohm & Haas' patent on a variety of grounds," which had not yet been decided in the district court. *Id.* at 185 & n.5. The possibility that the patent might ultimately be found invalid—as it later was, *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556 (Fed. Cir. 1983)—did not affect whether the challenged restraint was within the scope of the patent. (Once the patent was invalidated, obviously, any existing patent licenses became void, and any subsequent tying arrangement would have been subject to normal antitrust scrutiny.)

Similarly, in *United States v. United States Gypsum Co.*, 333 U.S. 364 (1948), the United States challenged patent licenses related to gypsum boards.

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[4] *Standard Oil* also considered whether the licensors had used their profit-pooling and royalty-fixing agreement to obtain a monopoly in gasoline itself (which would have been beyond the scope of their patents on gasoline cracking processes), and held that they had not. 283 U.S. at 174-79.

There was no dispute that, "in the absence of whatever protection is afforded by valid patents[,] the licensing arrangements described would" violate the antitrust laws. *Id.* at 386. Although the Court held that the government had standing on remand to challenge the patents' validity and thus void the licenses, the Court also held that unless and until the government proved that "the asserted shield of patentability does not exist," the antitrust analysis "must be considered on a record that assumes the validity of all the patents." *Id.* at 388. The licenses were held to violate the antitrust laws because they imposed restrictions "beyond any patent privilege," not because the patents might have been invalid or not infringed. *Id.* at 391.

C. The Scope-Of-The-Patent Rule Follows This Court's Precedents

The lower courts' scope-of-the-patent rule is a direct application of the principles embodied in these precedents. Antitrust scrutiny is limited to patent settlements involving restraints exceeding the scope of the patent, fraudulently obtained patents, or sham patent assertion.

1. The FTC insists that the proper antitrust analysis must discount the patent's exclusionary force to account for the possibility that it might be held invalid or not infringed. But the FTC cites no case of this Court discounting a patent's exclusionary scope merely because the patent later might be found invalid or not infringed. Such an approach would effectively eliminate every patent's exclusionary power because every patent, even a patent that has already been found valid in one case, *might* be found invalid in another case involving a different accused infringer.

Rather, this Court's precedents show that it is irrelevant if an antitrust challenge to a patent settlement arises against the backdrop of a patent whose validity and infringement was contested but undecided. Although the Court's precedents have addressed a diverse variety of alleged restraints, they all indicate that the antitrust analysis "must be considered on a record that assumes the validity of all the patents involved," unless and until the patent claim is rejected. *Gypsum*, 333 U.S. at 388.

2. The FTC is wrong in contending that the scope-of-the-patent rule treats Hatch-Waxman settlements as "per se lawful." FTC Br. i. First, the rule does not protect settlements involving fraudulently acquired patents or sham litigation, so it safeguards the public from being "repressed by worthless patents." *Id.* at 48.

Second, the rule does not protect settlements that restrain competition beyond the potential impact of the patent litigation. For example, courts condemn patent settlements that seek to control obviously non-patented products. *See, e.g.*, *King Drug Co. of Florence v. Cephalon, Inc.*, 702 F. Supp. 2d 514, 534 (E.D. Pa. 2010) (denying motion to dismiss because the complaints alleged that the settlements excluded "products not covered by any of Cephalon's patents"). In the Hatch-Waxman context, courts subject settlements to antitrust scrutiny to ensure they do not go beyond the patent's scope by including terms that block future ANDA filers in a manner that exceeds the restrictions adopted by Congress. *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1311-12 (11th Cir. 2003) (generic company's agreement never to waive its 180-day exclusivity period made settlement potentially anticompetitive); *King Drug*, 702 F.

Supp. 2d at 532-33 (denying motion to dismiss because complaints alleged "creation of a bottleneck" through generics' "agree[ment] not to give up their 180-day exclusivity").[5]

3. The FTC is also incorrect when it suggests (FTC Br. 36, 48) that the scope-of-the-patent rule conflicts with the rule permitting licensees to challenge patents notwithstanding contrary license terms. *See, e.g.*, *Lear, Inc. v. Adkins*, 395 U.S. 653, 673-74 (1969). Any policy favoring the testing of patents does not apply to litigation settlements, which, to be meaningful, must include a release by the accused infringer. *See, e.g.*, *Hemstreet v. Spiegel, Inc.*, 851 F.2d 348, 350 (Fed. Cir. 1988). *Lear* does not displace the strong public policy favoring finality of litigation and private resolution of disputes.

4. Under the scope-of-the-patent rule, the FTC's complaint fails to state a claim. It does not allege sham litigation or *Walker Process* fraud, and the FTC concedes that the challenged agreements "contemplated a greater degree of generic competition than might have occurred if the case had been litigated to judgment and the patentee (Solvay) had prevailed"—which would have excluded Watson's and Paddock's products for five additional years, until 2020. FTC Br. 43 n.10. The challenged restraint is thus within the scope of Solvay's patent.

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[5] Here, Watson expressly relinquished its 180-day exclusivity as part of the settlement.

II. THE FTC'S PROPOSED TEST IS UNPRECEDENTED AND UNJUSTIFIED

A. The FTC Is Asking For A Rule Of *Per Se* Illegality

The FTC largely ignores the law discussed above and instead asks the Court to treat any patent settlement with a "reverse payment" as presumptively illegal. It asserts that the presumption of illegality can be rebutted by only one of three showings: (1) the reverse payment was "bona fide fair consideration" for something "unrelated to the brand name manufacturer's monopoly"; (2) the "reverse payment" was less than "avoided litigation costs"; or (3) other "rare" circumstances of "unusual business or litigation justifications," such as a "modest cash payment that enables a cash-starved generic manufacturer to avoid bankruptcy and begin marketing a generic." FTC Br. 37-38.

Although the FTC describes its proposed rule as an application of "quick-look" analysis, it would actually impose *per se* illegality. The FTC's first two forms of permitted "rebuttal" require showing that, in fact, there was no reverse payment—the first by showing that there was no net "payment" because the exchange was at fair market value, and the second by showing that any "payment" was de minimis. The third permitted form of rebuttal is both "rare" (by the FTC's admission) and undefined; it certainly is not "clear enough for lawyers to explain to clients," *Pac. Bell Tel. Co. v. linkLine Commc'ns, Inc.*, 555 U.S. 438, 453 (2009), or for courts to apply. The FTC's only example—saving a generic company from bankruptcy—is unrealistic; rational patentees would not fund such a potential competitor.

While the FTC says it does not support a *per se* rule of illegality for reverse-payment patent settlements, the inability to rebut the presumption of illegality by showing there likely would be no anticompetitive effect is the very essence of *per se* analysis.

B. The FTC's Test Is Not Supported By Precedent

1. Especially when viewed as the rule of *per se* condemnation that it is, the FTC's rule cannot be supported. The Court adopts *per se* rules only after "courts have had considerable experience with the restraint" and that experience shows the restraint is always or almost always anticompetitive. *Leegin*, 551 U.S. at 886. The FTC has not shown any judicial experience, much less "considerable" experience, finding "reverse-payment" settlements anticompetitive. To the contrary, until the Third Circuit's decision last year in *In re K-Dur Antitrust Litigation*, 686 F.3d 197 (3d Cir. 2012), every circuit to consider the issue had found "reverse-payment" settlements to be lawful unless they contained exclusionary terms that exceeded the scope of the patent. *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 104-08 (2d Cir. 2010) (per curiam); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336-37 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 205-09 (2d Cir. 2006); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1066 (11th Cir. 2005); *Valley Drug*, 344 F.3d at 1312.[6]

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[6] The Sixth Circuit had previously held a Hatch-Waxman settlement *per se* illegal, *see In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), but that settlement contained

2. Even treated as a "quick-look" analysis, the FTC's proposed rule cannot be supported. This Court has only applied a "quick-look" analysis to arrangements that "resemble[] practices" that are *per se* unlawful. *E.g.*, *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 458 (1986); *see also* 11 Areeda & Hovenkamp, *supra*, ¶ 1911c, at 335. The FTC argues that a "reverse-payment" patent settlement "closely resembles" a *per se* illegal horizontal agreement, citing cases concerning horizontal price-fixing and market allocation in the absence of a patent. FTC Br. 20-24, 35. But the patent cannot simply be ignored. *See supra* § I; *see also E. Bement & Sons v. Nat'l Harrow Co.*, 186 U.S. 70, 88 (1902) ("The first important and most material fact in considering this question [antitrust analysis of patent-related agreements] is that the agreements concern articles protected by letters patent of the government of the United States."). This Court has never treated a patent-related restraint as a market allocation that can be condemned under a *per se* or quick-look analysis, rather than examining whether the restraint is within the scope of the patent. Cases such as *General Electric*, *Standard Oil*, and *Gypsum* show that conventional antitrust analysis does not apply where, as here, the challenged restraints are within the scope of the patent.

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competitive restraints that exceeded the scope of the patent, *see Tamoxifen*, 466 F.3d at 213-15 (distinguishing *Cardizem*); U.S. Br. at 11-15, *Andrx Pharms., Inc. v. Kroger Co.*, 540 U.S. 1160 (2004) (No. 03-779) (filed July 9, 2004) (explaining that the *Cardizem* settlement "extended beyond the legitimate scope of the patent claims").

Even the FTC implicitly recognizes this by endorsing patent-term split settlements, where the accused infringer agrees to stay off the market for some period. FTC Br. 27-28. Such an agreement would be a *per se* illegal horizontal market allocation in the absence of the patent but is indisputably legal in settlement of a bona fide patent dispute.

The FTC relies heavily on *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46 (1990). But nothing in *Palmer* suggests that antitrust law should ignore the potential exclusionary force of a patent or other intellectual property. That issue did not even arise in the case. *Palmer* concerned two competing bar-exam course providers that agreed not to compete in their respective geographies. The only property right mentioned was one defendant's trademark, but the defendants did not and could not claim that excluding all bar-exam preparation services, even those using a different mark, was within the scope of that trademark. Thus, the restriction was a naked market division, unsupported by a claim that it was within the scope of any intellectual property right. *Cf.* 12 Areeda & Hovenkamp, *supra*, ¶ 2044e2, at 317 (discussing how the restraint in *Palmer* was not "commensurate with the property right").

The error in the FTC's analysis is evidenced by the prior views of the United States itself, which previously argued to this Court that "the statutory right of patentees to exclude competition within the scope of their patents[] would potentially be frustrated by a rule of law that subjected patent settlements involving reverse payments to automatic or near-automatic invalidation." U.S. Br. at 11, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273) (filed May 17, 2006).

C. The FTC's Assumption Of Anticompetitive Effect Ignores That Many Patents Are Valid And Infringed

1. Neither a quick-look nor a *per se* rule is appropriate here because many "reverse-payment" settlements will have procompetitive effects. *See Leegin*, 551 U.S. at 886 (2007); *Cal. Dental*, 526 U.S. at 770-71 (quick-look analysis appropriate only when "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect" and when the "anticompetitive effects can easily be ascertained"). If a patent is actually adjudicated valid and infringed, for example, a settlement that provides for entry before patent expiration will *increase* generic competition, regardless of any "reverse payment."

This is hardly a theoretical criticism. Two of the leading reverse-payment antitrust cases of the past decade, *Tamoxifen* and *Ciprofloxacin*, involved settlements in which the generic company agreed to stay off the market and the patentee paid it tens of millions of dollars. *Tamoxifen*, 466 F.3d at 193; *Ciprofloxacin*, 544 F.3d at 1328-29. The FTC's rule would quickly condemn these settlements as illegal. But, in each instance, multiple additional generic applicants challenged the patent, the later patent litigation was not settled, and the patent was upheld. *See Tamoxifen*, 466 F.3d at 195; *Ciprofloxacin*, 544 F.3d at 1329.

The FTC acknowledges that a settlement allowing generic entry before the expiration of a valid and infringed patent *increases* competition. *See* FTC Br. 43 n.10. Under the FTC's approach, however, the

Tamoxifen and *Ciprofloxacin* settlements would be condemned as illegal notwithstanding that in each case courts held the patentee had an absolute legal right to exclude all infringing products. This cannot be correct. Neither the infringer nor consumers have the right to competition that violates a valid patent.

2. This central tension in the FTC's rule—that a "reverse-payment" settlement will be condemned even though the patent might be valid and infringed—may explain the government's inconsistent positions about whether antitrust analysis requires relitigating the patent dispute. The FTC first argued that antitrust courts should not determine the merits of the patent dispute because doing so would create "serious uncertainties" for "parties who seek to settle patent litigation." *In re Schering-Plough Corp.*, 136 F.T.C. 956, 993-98 (2003). In the same case, however, the United States argued before this Court that "an appropriate legal standard should take into account the relative likelihood of success of the parties' claims." U.S. Br. at 11, *Schering*, *supra*.

In 2009, the United States switched positions and argued that it was "not appropriate" to inquire into the likelihood of success on the merits. U.S. Br. at 24, *Ark. Carpenters*, 604 F.3d 98 (No. 05-2851) (filed July 6, 2009). But that same year, the FTC brought this case, arguing that antitrust analysis should turn on whether "it is more likely than not that the patent would not have blocked generic entry earlier than the agreed-upon entry date." Pet. App. 29a; *see also FTC v. Watson Pharms., Inc.*, 611 F. Supp. 2d 1081, 1088 (C.D. Cal. 2009) (noting that the FTC admitted "it could not litigate this case without also including

a theory of competitive harm that would necessitate looking to the merits of the patent cases").

Although the FTC and the United States now agree (as do all parties) that the patent merits should not be part of the antitrust analysis, the FTC's proposed rule still cannot avoid the paradox of condemning settlements as anticompetitive even if they result in generic entry earlier than the patent otherwise provides.

3. The FTC's response is to disparage patents and the PTO, suggesting most pharmaceutical patents are invalid. The sole support for this proposition is the FTC's own decade-old study concluding that, during the period 1992-2002, more than 70% of fully litigated pharmaceutical patent claims were defeated, and a more recent academic study concluding that 46% of patents are held invalid. FTC Br. 4, 6, 26. But the FTC's statistics are outdated and unreliable. *See* Br. of Antitrust Economists as Amici Curiae in Supp. of Resp'ts. Moreover, the academic study that the FTC cites—conducted by one of its amici—also found that 72% of *pharmaceutical* patents had been held *valid*. John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 217 (1998). And a more recent study with a larger sample shows that patentees win Hatch-Waxman cases more than half the time. RBC Capital Mkts., *Analyzing Litigation Success Rates* 1 (2010).

More fundamentally, statistics about patent cases litigated to conclusion are beside the point here, where the issue involves patent cases that are *not* litigated to conclusion. The FTC offers no data or analysis of the supposed "strength" of the patents in those cases. Indeed, the government itself has

previously recognized that the "gross disparities in the litigants' respective risks may . . . make reverse payments more likely, even when the patentee's legal claims are strong." U.S. Br. at 10, *Schering*, *supra*.

4. The FTC also derides many pharmaceutical patents as "secondary" or "trivial" because they cover improvements to or new formulations of a drug, rather than the active ingredient. FTC Br. 7, 44. There is no legal or factual basis for a rule that is premised on ranking some patentable inventions as more worthy of protection than others. The relief specified in Hatch-Waxman for patent infringement—exclusion of the generic drug for the entire patent term, 21 U.S.C. § 355(j)(5)(B)(iii)(II); 35 U.S.C. § 271(e)(4)(A)—applies regardless of whether the patent covers an improvement or formulation rather than the active ingredient, as do the patent laws generally. *See* 35 U.S.C. § 101. *Standard Oil*, *Dawson*, and *Gypsum* all involved "secondary" patents on new formulations or new processes for using or obtaining well-known chemicals. The Court did not suggest that these patents were entitled to less antitrust deference. Rather, the Court explained in *Dawson* that "[d]evelopment of new uses for existing chemicals" is a "major component of practical chemical research," with immense social value. 448 U.S. at 220-21.

AndroGel itself demonstrates how important a new formulation can be. Although testosterone has been known for decades, no one before Solvay had developed a dosage form that both was convenient and ensured a steady level of testosterone in the blood. This new formulation dramatically expanded the population of afflicted patients treated for their condition. It is for physicians and the marketplace,

not the FTC, to determine whether an invention is important or trivial.

It is equally misguided to suggest that antitrust law should categorize some pharmaceutical patents as "weak." The courts are not "warranted in assuming, in absence of a definite adjudication, that one grant by the Patent Office is more valid than another." *Masonite*, 316 U.S. at 280. Although the terms "strong" and "weak" may be bandied about in casual discussions of patents, there is no meaningful way to define these categories, or any reliable method of sorting patents into such categories.

In any event, Congress is the proper branch of government to address any perceived concerns about the patent system. *See Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2251-52 (2011). Congress has done so repeatedly, providing *ex parte* reexamination and *inter partes* review procedures that any person or entity can invoke to challenge a patent's validity. *See* 35 U.S.C. §§ 302-307; Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 6(a), 125 Stat. 284, 299 (2011).[7]

D. The FTC Cannot Demonstrate That "Reverse-Payment" Settlements Are Generally Anticompetitive

1. The FTC insists that the antitrust analysis should disregard the potential or actual exclusionary scope of patents and instead focus on a single supposed fact: that "reverse payments" are exchanged

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[7] Likewise, the United States itself has standing to challenge a patent's validity by bringing an antitrust challenge to a patent-related restraint. *Gypsum*, 333 U.S. at 386-88.

for later entry dates. Remarkably, the FTC has no persuasive evidence that establishes this proposition, despite studying "reverse payments" for almost 15 years and possessing detailed information on almost every Hatch-Waxman settlement since 2003. *See supra* p. 3. A demand that longstanding precedent be shunted aside in favor of a new presumption of illegality should require a very persuasive showing. *See Times-Picayune Publ'g Co. v. United States*, 345 U.S. 594, 621 (1953) (government cannot show "deleterious effects on competition" in Section 1 case with inconclusive evidence because "guilt cannot rest on speculation").

2. While the FTC characterizes its assumption that settlements delay entry as "natural" and "presumptive," FTC Br. 36, 38, the only evidence it provides is an FTC study concluding that the average settlement with a "reverse payment" provided for generic entry 17 months later than settlements without reverse payments. But the FTC has chosen not to release the study or any of the underlying data for independent evaluation, and instead relies in this Court on a public summary of its undisclosed analysis. *See* FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 7 (2010).[8] The Court should not give weight to any litigant's characterization of the results of its own private study.

Moreover, the FTC's report is flawed on its own terms. *See* Bret Dickey, Jonathan Orszag & Robert Willig, *A Preliminary Economic Analysis of the Budgetary Effects of Proposed Restrictions on 'Reverse*

[8] www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.

Payment' Settlements (2010).[9] The FTC study observes that agreements with what it characterizes as "reverse payments" have, on average, entry dates 17 months later than those with just a patent-term split. But this hardly proves the point the FTC is trying to make, because it assumes *causation* (that reverse payments cause entry delays) from purported evidence of nothing more than *correlation*. *Id.* Moreover, the FTC's analysis does not even control for the length of each patent's remaining term. A patent with 15 years remaining (as Solvay's patent had) is treated the same as one with one year remaining, even though the former is obviously much more likely to result in an agreement with later generic entry measured from the date of settlement. *See id.*

It may well be that the FTC has it exactly backwards. Instead of "reverse payments" causing longer entry delays, as the FTC assumes, it may be that "reverse payments" are caused by potential entry dates (based on the parties' estimates of the likely litigation outcome and the remaining length of the patent term) that are far into the future. For example, if the generic company has to wait 10 years before entry, it might require additional compensation given the risks that the market might shift to another drug in that time, or that it would no longer be operating under the same corporate ownership by then, or because its management compensation is based on short-term profits. Absent compensation, a generic company might prefer to play the litigation lottery based on a small possibility of a big victory,

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[9] www.compassleconecon.com/highlights/Documents/Dickey%20Orszag%20Willig%20CBO.pdf.

rather than wait for an agreed entry date that fairly reflects its chances in the litigation. Economists recognize that companies do not make decisions simply by multiplying probabilities by potential payoffs. *See* Bret Dickey, Jonathan Orszag & Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 Annals Health L. 367, 392-93 (2010); Willard K. Tom & Alexis J. Gilman, *U.S. and E.C. Antitrust Approaches to Patent Uncertainty*, 34 Law & Pol'y Int'l Bus. 859, 878-79 (2003).[10]

Thus, reverse payments may be necessary to achieve settlements that actually reflect what the FTC calls the "strength" of the patent, by compensating for the unique interests of accused infringers that are separate and apart from the patent merits. Certainly the FTC has presented no evidence otherwise. And the Government itself has previously recognized this possibility: that the "gross disparities in the litigants' respective risks may . . . make reverse payments more likely, even when the patentee's legal claims are strong." U.S. Br. at 10, *Schering*, *supra*.

Placing a scarlet letter on "reverse-payment" settlements could thus harm not only long-term consumer welfare (by weakening the incentives to

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[10] In addition, the 17 month calculation appears to assume that cases that settled with "reverse payments" could have settled without them and with an earlier entry date for the generic. But without reverse payments, many cases likely would not settle at all. *See infra* § IV.C. In those circumstances, if the patentee would succeed through litigation in keeping the generic off the market for the remainder of the patent term, the payment would have sped, not slowed, generic entry.

innovate, *infra* pp. 35-36) but also short-term consumer welfare (by eliminating settlements with earlier generic entry than the likely outcome of full litigation). *See* Dickey, Orszag & Willig, *supra*, at 4-5 (explaining this point and numerous other criticisms of the FTC's study).

The true relationship among "reverse payments," agreed-upon entry dates, and consumer welfare is not obvious, and the possibility that "reverse payments" enhance competition precludes *per se* or presumptive condemnation of such settlements. *See Cal. Dental*, 526 U.S. at 771, 775 n.12 (quick-look analysis is inappropriate where restraint "might plausibly be thought to have a net procompetitive effect, or possibly no effect at all on competition" or where "[a]s a matter of economics [the procompetitive] view may or may not be correct, but it is not implausible"); *Major League Baseball Props., Inc. v. Salvino, Inc.*, 542 F.3d 290, 340 n.10 (2d Cir. 2008) (Sotomayor, J., concurring in the judgment) (quick-look analysis is inappropriate when "empirical analysis is required to determine a challenged restraint's net competitive effect").

3. The FTC criticizes reverse payments as giving accused infringers something "they could not hope to obtain even if they prevailed in the litigation." FTC Br. 30. But this is beside the point. For example, no litigation outcome would have produced the cross-licenses and royalty-sharing provisions in the *Standard Oil* settlements. The relevant issue for purposes of assessing anticompetitive effect is whether the *exclusion* obtained by the patent holder is beyond what could have been obtained in the litigation. *See Valley Drug*, 344 F.3d at 1309 ("The failure to produce [a generic], rather than the payment of money,

is the exclusionary effect, and litigation is a much more costly mechanism to achieve exclusion, both to the parties and to the public, than is settlement.").

E. The FTC Ignores The Critical Benefits Of Innovation

A key premise of the FTC's arguments is that a presumption of unlawfulness will "enhance consumer welfare." FTC Br. 39. This argument rests on a flawed, myopic understanding of consumer welfare. It focuses exclusively on alleged short-term pricing effects (static efficiency), and disregards long-term innovation effects (dynamic efficiency). The reality is that the FTC's rule will make it harder to settle Hatch-Waxman cases, which will in turn decrease incentives for pharmaceutical research and also new generics. The FTC has not even attempted to show that its rule would have a net positive effect on consumer welfare.

1. The FTC admits that some cases that have settled with reverse payments would not otherwise have settled. FTC Br. 40. Indeed, the FTC has concluded that settlement rates doubled after the lower courts rejected the FTC's rule and adopted the scope-of-the-patent rule. *See* FTC, *Pay-for-Delay*, *supra*, at 9-10 (concluding that Hatch-Waxman settlement rates increased from 7% to 18% after the Eleventh Circuit's *Schering* decision).

If patent cases are harder to settle and patentees must more often roll the dice in litigation, the value of patents will decline. The ability to derive value from patents by bringing and settling litigation in good faith necessarily factors into business decisions to invest hundreds of millions of dollars or more to develop new drugs. *See Valley Drug*, 344 F.3d at

1308 ("restricting settlement options, which would effectively increase the cost of patent enforcement, . . . would impair the incentives . . . and innovation").

Strong patent rights are a prerequisite to continued pharmaceutical innovation. A reduction in the value of patents will lead to a reduction in investment. *See* Hon. Richard D. Cudahy & Alan Devlin, *Anticompetitive Effect*, 95 Minn. L. Rev. 59, 79-80 (2010) (noting that the pharmaceutical industry "would largely cease to exist but for patent protection"). The FTC's rule therefore would decrease investment in pharmaceutical innovation. Moreover, if it is harder to settle cases, such that expected Hatch-Waxman litigation costs are much higher, the cost of attempting to bring a generic version of a patented drug to market will increase, thereby disincentivizing development of generic products. *See* Br. for Generic Manufacturers as Amici Curiae in Supp. of Resp'ts.

2. Antitrust analysis must consider both static and dynamic procompetitive benefits, rather than privileging one over the other. *See* Thomas O. Barnett, Assistant Attorney Gen., Antitrust Div., U.S. Dep't of Justice, Recent Development in Antitrust and Intellectual Property Law 5-6 (May 16, 2007) ("[Because] technical change (dynamic efficiency) accounts for a large share of efficiency, growth, and welfare gains, antitrust enforcers should seek to ensure that their actions promote—and not inadvertently reduce—the forces that lead to technical change in the long term.");[11] *see also* Joseph E. Stiglitz & Carl E. Walsh, *Economics* 457 (4th ed.

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[11] www.justice.gov/atr/public/speeches/223390.pdf.

2006) (the "overall efficiency of the economy requires harmonizing" both short-term and long-term effects). A *per se* or quick-look rule is appropriate only where either past judicial experience or compelling empirical evidence decisively shows that a practice is always or nearly always anticompetitive. Thus, even if the FTC's rule would accelerate generic entry in some particular instances (which is speculative), that benefit would have to be shown to exist in nearly all cases and also weighed against the degree to which "*future* consumers will be harmed by reducing the flow of new pharmaceuticals to the market." James W. Hughes et al., *'Napsterizing' Pharmaceuticals: Access, Innovation, and Consumer Welfare* 2 (Nat'l Bureau of Econ. Research, Working Paper No. 9229, 2002) (emphasis added).

The FTC has not begun to make such a showing. Rather, it urges the Court to adopt its untested rule while ignoring the drag it could have on long-term consumer welfare. But innovation—and investment in innovation—can be more important to long-term consumer welfare than are lower prices. As Judge Easterbrook has put it:

> An antitrust policy that reduced prices by 5 percent today at the expense of reducing by 1 percent the annual rate at which innovation lowers the costs of production would be a calamity. In the long run a continuous rate of change, compounded, swamps static losses.

Frank H. Easterbrook, *Ignorance and Antitrust*, *in* Antitrust, Innovation, and Competitiveness 119, 122-23 (Thomas M. Jorde & David J. Teece eds., 1992).

The FTC estimates that "reverse-payment" settlements cost American consumers "$3.5 billion annually." FTC, *Pay-for-Delay*, *supra*, at 8. Even taking that estimate as true,[12] it would only amount to less than 2% of the $245 billion spent domestically on pharmaceuticals in 2011. FTC Br. 7. So even if all of the supposed "costs" of reverse payments were eliminated, the savings might be swamped by the resulting harm from even a tiny decrease in pharmaceutical investment and innovation.

III. THE FTC'S RULE IS NOT ADMINISTRABLE AND WOULD RADICALLY EXPAND ANTITRUST LIABILITY

A. Under The FTC's Rule, Parties To Antitrust Suits Would Need To Relitigate The Patent Merits

1. All parties agree that the antitrust standard for evaluating Hatch-Waxman settlements must not require relitigating the underlying patent dispute. After years of taking conflicting positions, including in the court below, the FTC now concedes that relitigating would be "likely unworkable in practice." FTC Br. 53. This accords with the conclusion of the court below that "'deciding a patent case within an antitrust case about the settlement of the patent case'" is an "'[un]palatable' 'turducken task.'" FTC Br. 54 (quoting Pet. App. 36a). No amicus in support of the FTC argues otherwise.

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[12] There are many reasons to think this $3.5 billion figure is exaggerated. It is entirely based, for example, on the faulty assumption that "reverse payments" delay generic entry by 17 months on average. *See supra* pp. 31-33.

As the FTC also now concedes, forcing relitigation of the patent case in a subsequent antitrust suit not only would be unworkable, but also would create a "powerful disincentive to settlement" because litigants would know that, in "settling" the patent dispute, they were likely just moving that entire dispute into one or more inevitable antitrust cases. FTC Br. 54.[13] Perhaps more importantly, forcing relitigation would magnify the risk of settlement by having treble-damage liability turn on a subsequent court's analysis of what the outcome of highly technical, uncertain patent litigation might have been. That is precisely the approach to antitrust scrutiny of patents that this Court rejected in *Walker Process*, 382 U.S. at 180 (Harlan, J., concurring) (antitrust liability should not turn on "one or more of the numerous technicalities" of patent law).

In addition to these undesirable effects, the "retrospective predict-the-likely-outcome-that-never-came" approach would be judicially unmanageable and unreliable. Pet. App. 33a. "It is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case." *Whitmore v. Arkansas*, 495 U.S. 149, 159-60 (1990). This is particularly true in patent litigation, the unpredictability of which is well documented.[14]

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[13] Forcing relitigation of the patent dispute would also increase the expense of antitrust litigation, which this Court has recognized as already quite significant. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 559 (2007).

[14] U.S. Court of Appeals for the Fed. Circuit, *Affirmance and Reversal Rates for District Court Patent Infringement Appeals*, www.patentlyo.com/files/caseload_patent_infringement_affirmance_and_reversal_rates_2001-2010.pdf (showing that over 40% of patent appeals result in reversal or vacatur at least in part).

2. Despite agreeing that it would be undesirable and unworkable to relitigate the patent merits in a subsequent antitrust case, the FTC candidly acknowledges, as it must, that its rule *would* require such relitigation for "[q]uantification of damages" in private antitrust actions. FTC Br. 55 n.11. The significance of this admission cannot be overstated. Private antitrust actions far outnumber those brought by the FTC and will be subject to whatever test the Court adopts in this case. Every "reverse-payment" challenge the FTC has initiated has been followed by droves of private-plaintiff lawsuits. This case alone gave rise to *thirteen* follow-on private-plaintiff cases. And private plaintiffs have brought dozens of "reverse-payment" challenges to settlements that the FTC never pursued, for drugs including Tamoxifen, Cipro, Effexor, Lipitor, Lamictal, and Nexium.[15] The FTC's proposed rule would thus mire the federal courts in years of litigation over the merits of patent disputes that were supposedly settled.

Moreover, this is not just an issue of the "quantification of damages." Under a genuine quick-look rule (or full rule-of-reason analysis), relitigating the patent case would need to occur even in cases brought by the FTC because no conclusion about a patent settlement's effect on competition could logically be reached without determining if the patent was likely valid and infringed. *See Cal. Dental*, 526 U.S. at 775 n.12 (under "quick-look" approach, defendant must have an opportunity to show "empirical

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[15] See, respectively, MDL No. 1408; MDL No. 1384; No. 11-cv-5590 (D.N.J); MDL No. 2332; No. 12-cv-5 (D.N.J); and MDL No. 2409.

evidence of procompetitive effects" that "offset anti-competitive effects").

Worse, under a true "quick-look" (or full rule-of reason) analysis, the patent merits would be relevant to determining not just who would have won, but the *odds*, at the time of settlement, that the patent claims would have been upheld. *See Tamoxifen*, 466 F.3d at 227 (Pooler, J., dissenting) (suggesting that liability would turn on assessment of "the ex ante likelihood of prevailing in [the] infringement lawsuit"). Those odds would then need to be compared with the patent-term split to see if the split fairly reflects the actual patent "strength." But it is obviously impossible for a jury to determine the "strength of the patent" reliably, particularly years after the fact.

In contrast, the scope-of-the-patent rule does not implicate relitigating the underlying patent dispute at all. If *Walker Process* (fraud on the PTO) or *PRE* (sham litigation) is alleged, the damages would be calculated from a baseline "but-for" world in which the patent litigation was never filed. *See* 2A Areeda & Hovenkamp, *supra*, ¶ 392e, at 336-37. If a restraint exceeds the scope of the patent, damages would be based on the market impact of that restraint, which (being outside the patent scope) should have little to do with the merits of the patent claims.

B. The FTC's Rule Will Render Many Ordinary Settlements Presumptively Illegal

Another problem with the FTC's proposed rule is that it is not possible to apply the concept of "reverse payments" in a principled, predictable manner. It is

striking that the FTC's and its amici's briefs fail to precisely define the term "reverse payments," even though the concept lies at the core of the FTC's theory. The reality is that there are no principled limits to that term, so the FTC's rule would condemn many typical settlements both inside and outside the pharmaceutical context. At bottom, the rule would give the FTC roving authority to challenge almost any settlement it believed could have been structured to provide more consumer benefits. Moreover, the FTC's rule would give *private* plaintiffs the same unbridled authority, with the added incentive of the potential for recovering treble damages and attorneys' fees.

1. The concept of "reverse payments" cannot be limited to specific types of transactions

Despite the FTC's use of "reverse payment" nomenclature, it is not seeking to condemn only naked cash payments. FTC Br. 27 (referring to "money or similar consideration"). No naked cash payments are present in either the settlements in this case or those challenged in several other cases. Rather, each settlement here includes a business deal in which Solvay, at the time a relatively small pharmaceutical company with a small sales force, paid the respective generic company to market AndroGel using its own sales forces or to provide manufacturing capacity to Solvay. Pet. App. 44a. Settlements in complex commercial cases routinely involve these kinds of cooperative business dealings to bridge the difference in the parties' respective litigation positions. The FTC alleges that these business deals constituted "reverse payments" because they delivered "value" to

the generics in one form or another, such as because Solvay "overpaid" for the services it received.

But if "reverse payments" include more than naked cash payments—if they include any "value" delivered to the accused infringer—then the FTC's rule cannot reasonably be limited. Over the past decade, neither the FTC nor any amicus has proposed a workable boundary around what constitutes a "reverse payment." *See* FTC Br. 36 n.7 (discussing "alternative form[s] of consideration" that would be subject to the same analysis).

Although not explicit in its briefs here, the FTC publicly advocates that a "reverse payment" cannot be limited to a monetary payment. If, for example, the patentee agrees as part of the settlement to supply the drug at issue or license another drug to the generic company—both seemingly procompetitive agreements—the FTC says those would be "reverse payments" and condemned. *See* FTC, Summary of Agreements Filed in FY 2009, at 4 (brand supplied generic with unrelated drug);[16] FTC, Summary of Agreements Filed in FY 2008, at 4 (license to sell authorized generic version of other drugs).[17] Even if the accused infringer paid for the license or the drug supply, it would be just as possible that the accused infringer was "underpaying" for those benefits as it is that Solvay "overpaid" for the services it obtained in this case.

Indeed, in half of the settlements that the FTC last year classified as involving a "reverse payment," the

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[16] www.ftc.gov/reports/mmact/MMAreport2009.pdf.

[17] www.ftc.gov/os/2010/01/100113mpdim2003rpt.pdf.

patentee merely agreed that its license to the generic infringer as part of a patent-term split would be exclusive as against the patentee—*i.e.*, the patentee would not market its own drug as a generic. FTC, Overview of Agreements Filed in FY 2012, at 1.[18] Such "no-authorized-generic" provisions merely ensure that the brand-name firm does not undercut the 180-day exclusivity period that Hatch-Waxman provides to the first generic, which the FTC itself touts as one way Congress sought to encourage patent challenges. FTC Br. 31. The FTC has asserted, however, that the exclusivity of the license is "value" to the generic infringer and therefore constitutes a presumptively illegal "reverse payment." As one Commissioner explained, "[w]hether a branded firm offers a [no-authorized-generic] commitment, its own stock, a license to an unrelated product, or an overt cash payment, *the economic reality is the same*: a generic receives compensation for delayed entry." J. Thomas Rosch, Comm'r, FTC, Remarks at CBI's 2nd Annual Life Scis. Compliance, Legal & Regulatory Congress 19-20 (Sept. 21, 2012) (emphasis added).[19]

If a "reverse payment" includes "anything of value" then even a standard royalty-bearing license with a deferred entry date would be a presumptively illegal "payment." After all, the generic company might have paid a higher royalty if the entry date had been earlier. For example, if an accused infringer chooses a $1-per-pill royalty with a 2017 entry date instead of a $2-per-pill royalty with a 2014 entry date,

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[18] www.ftc.gov/os/2013/01/130117mmareport.pdf.

[19] www.ftc.gov/speeches/rosch/120921cbipharmaspeech.pdf.

plaintiffs will argue that consumers would have been better off with the latter choice.

Almost no settlement term—certainly no business deal—appears to be immune from potential classification as a "reverse payment." Enterprising plaintiffs could argue even that agreeing to a generic company's preferred terms regarding damage caps, attorneys' fees, and the like—provisions with real economic value—presumptively violates the antitrust laws because the generic company could have been induced to accept a slightly later entry date in exchange for those settlement terms.

It is not that the FTC has chosen an overbroad definition of "reverse payments," but that there is no principled limit to the concept of a "reverse payment" because it logically includes "economic value to the challenger in any form." FTC C.A. *En Banc* Pet. 13. That logic forces the rule to condemn *any* business deal or settlement term favorable to the generic company.

2. The FTC's rule could not be limited to the Hatch-Waxman context

The concept of presumptively illegal "reverse payments" would outlaw even routine settlements—including outside the Hatch-Waxman context—in which a patentee compromises a damage claim in exchange any market exit by the accused infringer. Releasing a party from potential liability is, from a legal and economic perspective, just as much the provision of "value" as cash or a business deal. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003) ("in the traditional context, implicit consideration flows from

the patent holder to the alleged infringer"); Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 Antitrust L.J. 1033, 1033 (2004) ("the patent holder 'pays' to settle by accepting less in damages from the infringer than it expects to get from litigating").

Although the FTC declines to address the issue explicitly, even the FTC's supporters acknowledge this. For example, the only source the FTC cites to explain the scope of "reverse payment" is an article by counsel for one of its certiorari-stage amici who also served as a consultant to the FTC on pharmaceutical issues. *See* FTC Br. 36 n.7 (citing C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Competition*, 109 Colum. L. Rev. 629, 633-66 (2009)). This article explains that a patent-term split with an agreement to compromise damages must be treated as presumptively illegal. The article offers several examples of such "payments," including the Lipitor settlement, in which Pfizer forgave the damages it claimed in a different patent lawsuit. Hemphill, *supra*, at 683. The article also discusses a settlement relating to the drug Solodyn, in which the generic company agreed to cease sales for two years in exchange for the patentee's agreeing to waive damages in the same case.[20] The article argues that this standard settlement structure constitutes a "reverse payment." *Id.* at 683-84 & n.228.

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[20] Damages had accrued in that case because the generic entered "at risk" after it received FDA approval but before the patent litigation had reached conclusion.

This is not a hypothetical but a live issue in litigation brought by the plaintiffs' antitrust bar. Antitrust actions have already been filed alleging that Pfizer's forgiveness of damages was a "reverse payment" to delay the entry of generic Lipitor. Direct Purchasers' Consolidated Am. Compl. ¶ 316, *In re Lipitor Antitrust Litig.*, No. 12-cv-2389 (D.N.J. filed Sept. 10, 2012).

The FTC asserts that "reverse-payment" settlements "appear to be essentially unknown outside the Hatch-Waxman context," FTC. Br. 18, but it presents no support for that assertion. Private patent settlements are confidential, so it is impossible to study them systematically. But there is no reason to assume that private patent settlements in other contexts never include "value" beyond the patent license itself. Rather, it stands to reason that they include compromises of damages and other business deals that confer value on the alleged infringer. The FTC's proposed rule would presumptively condemn these patent settlements.

3. The FTC's purported "rebuttal" opportunity is impractical

To make its rule more palatable, the FTC states that defendants could "rebut" the presumption of illegality by showing that exchanges were of commensurate value. FTC Br. 37. But settlement agreements rarely quantify in dollars the various elements or concessions provided each side, and, even if they did, such a quantification could itself be disputed in later antitrust litigation under the FTC's rule. The end result is that the "rebuttal" opportunity would spur years of litigation in essentially every case about what the value was given "for."

Indeed, the FTC states that courts would need to consider at least *five factors* in the rebuttal analysis, including "whether the payment reflected bona fide fair consideration," whether the "other terms of the side transaction comported with industry standards," and the previous dealings between the parties. FTC Br. 37-38. At least the first two of these factors would involve testimony by experts, whose inevitable disagreements could preclude summary judgment and require high-stakes, expensive, and unpredictable litigation all the way through jury trial.

Moreover, the standard to be applied to these often one-of-a-kind transactions is unclear. The FTC says the property or services would have to be "unrelated to the brand name manufacturer's monopoly." FTC Br. 37. But the FTC nowhere explains what "unrelated" means or why it would make the deal less likely to be "for delay," in the FTC's parlance. And even if the consideration provided by the patentee in a contemporaneous business deal could be shown to exceed the consideration provided by other companies for similar products or services in other circumstances, that would not necessarily mean the deal was a disguised payment. For example, Solvay could have concluded that Watson would make a more concerted effort to develop the AndroGel market than a third party because Watson will inherit that market in 2015. *Cf. Town of Concord v. Boston Edison Co.*, 915 F.2d 17, 25 (1st Cir. 1990) (Breyer, C.J.) (explaining why antitrust law should not depend on a test involving determination of a "fair price" when no "other suppliers of the primary product" exist, and asking "how is a judge or jury to determine a 'fair price?'").

C. Congress, Not The Courts, Should Address Any Proposals For Industry-Specific Rules

Perhaps concerned about the difficulty of applying the FTC's rule broadly, the Third Circuit tried to limit this new antitrust rule to the pharmaceutical industry. *K-Dur*, 686 F.3d at 216. (The FTC's brief appears to take no position on such a limitation.) But the problems posed by the boundless concept of "reverse payment" cannot properly be addressed by artificially limiting the proposed new rule to the pharmaceutical industry. Antitrust statutes are "law[s] of general application." *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 640 (1994). In providing the "substantive content" of antitrust law, the Court has been careful to "adher[e] to rules that are justified in their general application." *Arizona v. Maricopa County Med. Soc'y*, 457 U.S. 332, 354 (1982).

Whether the FTC's new rule is understood as a *per se* rule or a "quick-look" analysis, any effort to confine it to a single industry would be in tension with this Court's precedents. *Per se* rules have "general application," *id.* at 344, and are designed to "treat[] *categories* of restraints as necessarily illegal." *Leegin*, 551 U.S. at 886 (emphasis added). The Court has similarly not confined its "quick-look" decisions to particular industries. *See Cal. Dental*, 526 U.S. at 770-71 (describing prior "quick-look" cases). Even in *National Collegiate Athletic Ass'n v. Board of Regents of the University of Oklahoma*, 468 U.S. 85 (1984), the Court did not create a "quick-look" rule limited to football or college sports, but rather framed its holding in broad terms, as applicable to an "industry in which horizontal restraints on competition are

essential if the product is to be available at all." *Id.* at 101.

This Court's reluctance to create industry-specific antitrust rules reflects "a recognition of the respective roles of the Judiciary and the Congress in regulating the economy." *Maricopa*, 457 U.S. at 354; *cf. United States v. Topco Assocs., Inc.*, 405 U.S. 596, 611-12 (1972). "By articulating the rules of law with some clarity and by adhering to rules that are justified in their general application," the courts "enhance the legislative prerogative to amend the law." *Maricopa*, 457 U.S. at 354. Parties seeking industry-specific rules "are better directed to the Legislature," which "may consider the exception[s] that [courts] are not free to read into the statute." *Id.* at 354-55; *see also Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 689-90 (1978) (arguments for special antitrust rules "for specific industries" are "properly addressed to Congress").[21]

When the Third Circuit relied on *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398 (2004), to support an industry-specific rule, it mistook the import of that case. *K-Dur*, 686 F.3d at 216. *Trinko* involved an antitrust challenge relating to breaches of express regulatory provisions. Instead of inventing a new antitrust rule specific to that regulated industry, the Court applied "pre-existing antitrust standards" to find that no violation had occurred. 540 U.S. at 407. When *Trinko*

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[21] *See generally* 1A Areeda & Hovenkamp, *supra*, ¶ 240a, at 272 (where a particular market is "thought to require more restriction on competition than others[,] Congress may then respond by enacting special statutes that modify, complement, or displace the competitive premises and rules of antitrust").

stated that antitrust analysis should "recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies," *id.* at 411, *quoted in* FTC Br. 30, it was merely a call for considering context when applying "pre-existing antitrust standards," *id.* at 407.

To the extent Congress views Hatch-Waxman settlements as raising unique or particular problems, it can adopt specific legislation to address those concerns. That Congress has repeatedly considered legislation in this area, *see infra* pp. 56-57, is powerful evidence that the FTC is better directed to Congress than to this Court in seeking to codify its preferred rule.

IV. POLICY CONSIDERATIONS DO NOT SUPPORT THE FTC'S RULE

In the absence of any precedent that genuinely supports its position, the FTC and its amici rely primarily on rhetorical policy arguments. These arguments are incorrect and unsupported.

A. The Scope-Of-The-Patent Test Does Not Diminish Generic Competition

The FTC and its amici warn that the scope-of-the-patent rule impedes generic entry because (1) later generic applicants without 180-day first-filer exclusivity lack incentives to pursue patent challenges, *e.g.*, FTC Br. 51-52; Apotex Br. 11-16; and (2) the scope-of-the-patent test allows innovator companies to "buy off" each generic company that comes along with a payment equal the generic company's potential profit, *e.g.*, FTC Br. 21. These arguments are inconsistent with experience and logic.

1. As an initial matter, the generic drug industry has been flourishing, including under the scope-of-the-patent rule that has prevailed for the last decade. When Hatch-Waxman was enacted in 1984, generic drugs accounted for 19% of all U.S. prescriptions; as of 2011, generics represented 80% of prescriptions, a fourfold increase. IMS Inst. for Healthcare Informatics, *The Use of Medicines in the United States: Review of 2010*, at 19 (2011);[23] Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 New Eng. J. Med. 1993, 1993 (2007).

2. Experience also shows that blockbuster drugs often face swarms of ANDAs, "even without the prospect of the exclusivity period." John M. Rebman, *Dr. Strange Drug, Or: How I Learned to Stop Worrying and Love Authorized Generics*, 12 DePaul J. Health Care L. 159, 180-81 (2009); *see also, e.g.*, *Pfizer Inc. v. Apotex Inc.*, No. 12-cv-808 (D. Del.) (consolidated Hatch-Waxman litigation involving more than ten ANDAs for Pristiq); *Pfizer, Inc. v. Teva Pharms. U.S.A., Inc.*, 882 F. Supp. 2d 643, 657-62 (D. Del. 2012) (describing patent lawsuits arising from eight generic companies' ANDAs for Lyrica); Bristol-Myers Squibb Co., Annual Report (Form 10-K), at 101 (Feb. 17, 2012) (describing Hatch-Waxman litigation against seven generic companies regarding Abilify). All of these examples took place at a time when *every* federal appellate court to have addressed the issue embraced the scope-of-the-patent test.

3. Nor is there any basis for the FTC's assertion that the scope-of-the-patent test encourages pharmaceutical companies to pay off every generic

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[23] www.rxobserver.com/?p=506.

challenger. If a brand-name company were willing—or even perceived as willing—to pay generic challengers "more than they could hope to earn if they entered the market," FTC Br. 21, it would attract a multitude of generic challengers, particularly if, as the FTC supposes, the patent were seen as unlikely to be upheld. Such a brand-name company would also invite economic holdup, as each generic company demanded payment exceeding its potential profits because the brand-name company stands to lose so much more.

Although the FTC cites instances in which there were two or three "reverse-payment" settlements involving generic versions of the same drug, FTC Br. 52, it does not offer a single example in which every generic applicant was paid all its profits, let alone data showing this to be a common practice. To the contrary, the FTC's own data show that a substantial majority of the Hatch-Waxman settlements in the last decade did not involve any kind of payment, even while the courts of appeals were uniformly adopting the scope-of-the-patent test. FTC Br. 47. Nor do its own data support the idea that filers subsequent to the first filer have been paid off. Instead, the FTC itself recently reported that "[s]ince 2004, 44 branded products have been involved in a potential [reverse-payment] settlement followed by at least one settlement containing no compensation to the generic. As many as nine generic companies have settled for no compensation following a potential [reverse-payment] deal on the same branded product." FTC, Overview of Agreements Filed in FY 2012, at 1 n.1.[23]

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[23] www.ftc.gov/os/2013/01/130117mmareport.pdf.

Innovator companies also have been known to litigate with second and later filers instead of settling. For example, after settling a Hatch-Waxman case with the respective first generic filer, the ciprofloxacin and tamoxifen patent holders each litigated numerous subsequent cases to judgment—and won them all. *See Ciprofloxacin*, 544 F.3d at 1328-29; *Tamoxifen*, 466 F.3d at 193-95.

B. The Hatch-Waxman Act Does Not Support The FTC's Rule

Like the Third Circuit, the FTC seeks support for its rule in the text and supposed purpose of the Hatch-Waxman Act. FTC Br. 30-33; *K-Dur*, 686 F.3d at 217. But the statute says nothing about settlement of paragraph IV litigation, and it certainly does not treat "reverse-payment" settlements as presumptively unlawful. Moreover, this Court must consider Hatch-Waxman "in the light of the purposes which led to the enactment of the entire legislation." *Southland Gasoline Co. v. Bayley*, 319 U.S. 44, 47 (1943). In that light, the Act cannot reasonably be construed as evincing a singular "goal . . . to increase the availability of low cost generic drugs." *K-Dur*, 686 F.3d at 217; *see also* FTC Br. 30-31.

Hatch-Waxman "respond[ed] to two unintended distortions of the 17-year patent term." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669 (1990). First, there was a concern that, as a result of the review process for new drugs, patentees were not being sufficiently rewarded because they could not "reap any financial rewards during the early years of the term." *Id.* Congress responded by extending the patent term by up to five years for certain products, 35 U.S.C. § 156, to "create a new incentive for increased expenditures for research and development,"

H.R. Rep. No. 98-857, pt. 1, at 15 (1984) (House Report).

Second, because generic companies could not "conduct[] tests and develop[] information necessary to apply for regulatory approval" during the life of the patent without infringing it, the development of generic drugs was delayed for many years after patent expiration. *Lilly*, 496 U.S. at 670. Congress responded by (1) adopting the expedited ANDA process, *see* 21 U.S.C. § 355(j); and (2) creating a safe harbor for generic manufacturers' research and development during the patent term, *see* 35 U.S.C. § 271(e)(1).

Thus, the primary goals of the bill were to strengthen patent rights while encouraging earlier development of generic drugs, so that the generics would be available soon after patent expiration. As Congressman Waxman explained:

> [T]he whole conceptuality of this bill is to give more time for the firm developing the patented drug, to give them a further incentive for research and development. There is a public good in that. The other side of it is to give the opportunity for competition in generic drugs to be on the market *after that patent has expired*.

130 Cong. Rec. 24,430 (emphasis added).[24] And when Congress provided procedures for litigating patent

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[24] To the extent that the FTC and Congressman Waxman attempt to "create[] legislative history through the *post hoc* statements of interested onlookers," they are "entitled to no

disputes, it did not intend to alter the patent laws or to inhibit settlements.[25] *See, e.g.*, House Report, *supra*, at 28 ("[P]rovisions of this bill relating to the litigation of disputes involving patent validity and infringement are not intended to modify existing patent law . . . .").

The FTC's characterization of Hatch-Waxman cannot be squared with this history. The FTC contends that the Act, including the 180-day exclusivity period, reflects a "policy" of "realizing the benefits of generic competition at the earliest appropriate time." FTC Br. 30-31. But that would come as a surprise to the 1984 Congress, which not only provided for extra years of patent protection, but also amended the bill before final passage to *lengthen* the stay on final approval of ANDAs that are subject to paragraph IV litigation from 18 months to 30 months. *See* 130 Cong. Rec. 24,430 (Rep. Waxman) (describing change and arguing in favor of it). While Congressman Waxman now asserts that an overriding purpose of the law was to encourage paragraph IV litigation, *see* Rep. Waxman Br. 15, he described the paragraph IV procedures at the time as "a side issue to the overall importance of this bill." 130 Cong. Rec. 24,430.

More recent evidence of legislative intent suggests that Congress does *not* view "reverse-payment" settlements as presumptively unlawful. Every Congress

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weight." *W. Air Lines, Inc. v. Bd. of Equalization*, 480 U.S. 123, 130 n.* (1987); *see* FTC Br. 31 & n.5; Rep. Waxman Br. 2.

[25] Similarly, nothing in the 2003 MMA legislation suggests that agreements featuring "reverse payments" are presumptively unlawful.

since 2006 has declined to pass bills that would address such settlements, including bills establishing a "presumption" of illegality. *See, e.g.*, S. 369, 111th Cong. § 3 (2009). Where Congress has "considered but rejected legislation that would endorse" an interpretation of a statute, it lends "support to [the] conclusion" that the statute should not be interpreted in that way. *Till v. SCS Credit Corp.*, 541 U.S. 465, 480 n.19 (2004). For example, the fact that Congress "repeatedly" introduced remedial legislation to respond to the antitrust exemption for professional baseball, but that "none has ever been enacted," rightly caused this Court to "conclude[] that Congress as yet has had no intention to subject baseball's reserve system to the reach of the antitrust statutes." *Flood v. Kuhn*, 407 U.S. 258, 283 (1972).

C. The FTC's Rule Will Preclude Settlements

Although the FTC imagines a world where "the parties to a Hatch-Waxman settlement simply agree upon a compromise date of generic entry," FTC Br. 27, basic principles of dispute resolution establish that a "straightforward settlement that simply splits the remaining patent term may not be available," Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles*, 15 Fed. Cir. B.J. 617, 629 (2006). When parties "negotiat[e] along a single dimension" and are prohibited from introducing other sources of value into the negotiation, there may be "no way to split the pie that leaves both parties satisfied." Roger Fisher et al., *Getting to Yes* 58 (3d ed. 2011); *see also* Br. of Mediation & Negotiation Professionals as Amici Curiae in Supp. of Resp'ts.

For example, a simple patent-term split may be impossible where the parties have different views about the likely outcome of the case, which is a common occurrence. Empirical studies demonstrate that "lawyers are poor predictors of the outcomes of their cases and tend to be over-confident concerning their chances of winning." Peter H. Schuck & E. Donald Elliott, *To the Chevron Station: An Empirical Study of Federal Administrative Law*, 1990 Duke L.J. 984, 1013 n.72. Where each side entertains inflated expectations about its chance of prevailing, there may be "a gap between the latest date at which the generic is willing to accept entry in order to settle litigation and the earliest date at which the innovator is willing to permit entry"—a gap rendering the case "impossible to settle within the [FTC's] patent-term-splitting paradigm." Bernard & Tom, *supra*, at 630.

Other factors may also make settling solely on a patent-term split impossible. For example, if a generic company sets its management's compensation based on short-term profits or stock price increases, or is considering selling the company, it may reject a patent-term split that provides no revenue in the short term, even if that split reflects the parties' expectations of success. If so, collateral terms, such as the licensing of other products, co-promotion agreements, or supply arrangements "may allow the brand-name and generic manufacturers to bridge the settlement gap" between their otherwise irreconcilable bargaining positions. Dickey, Orszag & Tyson, *supra*, at 394. But *all* of these terms would be treated as presumptively unlawful "reverse payments" under the FTC's rule.

The FTC downplays the significance of the fact that its rule will inhibit settlement. *See* FTC Br. 47-48. But "[t]here is no question that settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation." *Tamoxifen*, 466 F.3d at 202 (quotation marks omitted). More importantly, by increasing the cost and uncertainty of patent litigation, the FTC's rule would undermine incentives for brand manufacturers to develop new drugs and would also limit the incentive of generic manufacturers to pursue new generic challenges.

CONCLUSION

The Court should affirm the judgment of the court of appeals.

Respectfully submitted,

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February 21, 2013

RESPONDENT'S BRIEF

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AND
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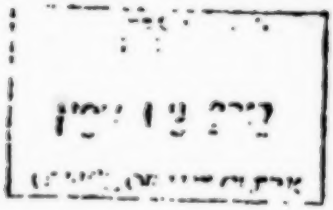

No. 12-416

In the Supreme Court of the United States

FEDERAL TRADE COMMISSION,
Petitioner,

v.

WATSON PHARMACEUTICALS, INC., ET AL.,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF FOR RESPONDENT WATSON PHARMACEUTICALS, INC.

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QUESTION PRESENTED

Whether the federal antitrust laws permit the settlement of patent litigation between a patent-holding brand-name pharmaceutical manufacturer and a generic manufacturer when the terms of the settlement do not exceed the potential exclusionary scope of the patent.

RULE 29.6 STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, Respondent Watson Pharmaceuticals, Inc., states the following:

Watson Pharmaceuticals, Inc., is a publicly held company that has no parent corporation, and no publicly held company owns 10% or more of its stock.

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BRIEF FOR RESPONDENT

Respondent Watson Pharmaceuticals, Inc. ("Watson") respectfully acquiesces in the petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Eleventh Circuit in this case (the "Petition").

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Eleventh Circuit is reported at 677 F.3d 1298 and is reproduced at Pet. App. 1a–36a. The opinion of the District Court granting respondent's motion to dismiss is available at 687 F. Supp. 2d 1371 and is reproduced at Pet. App. 37a–61a.

JURISDICTION

The judgment of the Court of Appeals was entered on April 25, 2012. A petition for rehearing was denied on July 18, 2012. Pet. App. 62a-63a. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Certain pertinent statutory and regulatory provisions are noted in the Petition and set out in the Petition Appendix. Pet. 2; Pet. App. 64a-122a. In addition to those provisions, 35 U.S.C. § 282 is also relevant and provides in pertinent part: "A patent shall be presumed valid."

INTRODUCTION AND STATEMENT OF THE CASE

The Government's Petition correctly identifies a disagreement among the courts of appeals over the appropriate antitrust analysis of patent litigation

settlements in the pharmaceutical context, and is correct in stating that this is a recurring question of great economic importance. The Government is incorrect, however, in asserting that the decision below should be reversed.

The court below held, consistent with its own precedent and with precedent from two other courts of appeals, that a final settlement of litigation to enforce a patent is immune from antitrust attack so long as the patent was not obtained by fraud, the litigation to enforce the patent was not a sham, and the alleged exclusionary effects of the settlement fall within the scope of the exclusionary potential of the patent. The Government would have this Court eschew this clear rule in favor of an ambiguous, incorrect, and burdensome rule adopted by the Third Circuit that deems certain patent settlements presumptively unlawful and improperly shifts the burden to the settling parties to demonstrate that their settlement does, in fact, violate the antitrust laws.

Because patent infringement litigation is a recurring feature of the statutory scheme applicable to the approval of generic drugs, and given the size and significance of the pharmaceutical industry in this country, the question presented is one of critical importance as to which there is a clear conflict among the circuits, with overwhelming authority against the Government's position. Respondent and the pharmaceutical industry as a whole require clarity as to the terms on which they may lawfully settle the litigation that is contemplated by statute. Respondent therefore acquiesces in the petition for certiorari.

1. The Food and Drug Administration ("FDA") regulates the manufacture, sale, and labeling of prescription drugs in this country. *See* 21 U.S.C. § 355. In order to obtain approval for a new drug, a brand-name pharmaceutical manufacturer must submit a New Drug Application ("NDA") to the FDA that demonstrates the safety and efficacy of its product. *See* 21 U.S.C. § 355(b). The approval process for generic drugs was set out by legislation known as the "Hatch-Waxman Amendments" in 1984. *See* Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585. The basic goal of the Hatch-Waxman Amendments was to balance the need for pharmaceutical innovation with the need for generic drug competition. *See, e.g., Teva Pharm. Indus. Ltd.* v. *Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005) ("[A]s even the formal name of the Hatch-Waxman Amendments (the Drug Price Competition and Patent Term Restoration Act) reflects, the Congress sought to strike a balance between incentives, on the one hand, for innovation, and on the other, for quickly getting lower-cost generic drugs to market.") Pursuant to the Hatch-Waxman Amendments, a generic manufacturer need not conduct extensive clinical trials for its generic product, but may instead submit an Abbreviated New Drug Application ("ANDA") that relies upon the safety and efficacy data in the brand-name manufacturer's NDA. *See* 21 U.S.C. § 355(j). In order to obtain approval, the ANDA must demonstrate, among other things, that the proposed generic product is bioequivalent to the brand-name drug. *See id.* § 355(j)(2)(A)(iv).

A brand-name manufacturer who submits an NDA must provide the FDA with the patent number and the expiration date of "any patent which claims

the drug ... or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1)(G); *see also* 21 C.F.R. § 314.53. If the NDA is approved, the FDA will list the patent in its so-called "Orange Book." *See* 21 C.F.R. § 314.53. Where there is a patent listed in the Orange Book for a given brand-name drug, a generic manufacturer's ANDA must contain a certification by the generic manufacturer with respect to that patent. *See* 21 U.S.C. § 355(j)(2)(A)(vii).

Relevant here is the so-called "Paragraph IV" certification, which is a statement alleging that the listed patent is invalid or unenforceable, that the generic version would not infringe the patent, or both. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The filing of a Paragraph IV certification is deemed a constructive act of patent infringement under Hatch-Waxman and thus gives the brand-name drug company the ability immediately to bring a patent infringement lawsuit against the ANDA filer. 35 U.S.C. § 271(e)(2)(A); *See also Caraco Pharm. Labs. Ltd.* v. *Novo Nordisk A/S*, 132 S. Ct. 1670, 1677 (2012) ("Filing a paragraph IV certification means provoking litigation.").

When such a lawsuit is filed within 45 days of receipt of notice of the Paragraph IV ANDA filing, the FDA may not grant final approval to the ANDA for 30 months after the lawsuit is filed or until the ANDA filer prevails in litigation, whichever occurs sooner. 21 U.S.C. § 355(j)(5)(B)(iii). On the other hand, if the brand-name drug company prevails, then the district court must issue an order preventing the

FDA approval from becoming final before the patent expires. *Id.* § 355(j)(5)(B)(iii)(II)(bb); 35 U.S.C. § 271(e)(4)(A).

Under Hatch-Waxman, the first ANDA filer for a generic version of the brand-name drug product is under certain circumstances entitled to 180 days of marketing exclusivity for its generic product, during which time the FDA will not grant final approval to subsequently-filed ANDAs. *See* 21 U.S.C. § 355(j)(5)(B)(iv). This 180-day marketing exclusivity, which can be quite valuable, serves as an incentive for generic manufacturers to challenge patents through a Paragraph IV ANDA.

2. The agreements at issue here relate to AndroGel, a brand-name prescription testosterone replacement drug used to treat a condition known as hypogonadism. FTC Complaint ¶¶ 1, 31-33;[1] Pet. App. 38a. AndroGel was developed and first marketed through the cooperative efforts of Besins Healthcare, S.A. ("Besins"), and Unimed Pharmaceuticals, Inc. ("Unimed"). *Id.* ¶ 32. Unimed was later acquired by Respondent Solvay Pharmaceuticals, Inc. ("Solvay").[2] *Id.* ¶ 16. The FDA approved Unimed's NDA for AndroGel in February 2000, and AndroGel came to market shortly thereafter. *Id.* ¶ 33; Pet. App. 39a.

Unimed and Besins applied for a patent on the AndroGel formulation and on methods of using that

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[1] The operative complaint, the Federal Trade Commission's ("FTC") Second Amended Complaint, is referred to herein for simplicity's sake as "FTC Complaint."

[2] Respondent Solvay was in turn acquired by Abbott Laboratories in 2010 and is now known as Abbott Products, Inc.

formulation in August 2000; the Patent and Trademark Office ("USPTO") granted the application and issued U.S. Patent No. 6,503,894 (the "'894 patent") in January 2003. FTC Complaint ¶¶ 39, 42. The '894 patent expires in August 2020. *Id.* ¶ 43. In May 2003, Respondent Watson submitted an ANDA containing a Paragraph IV certification, seeking FDA approval to market a bioequivalent, generic version of AndroGel.[3] *Id.* ¶ 44. Respondent Paddock Laboratories, Inc. ("Paddock"), filed its own Paragraph IV ANDA shortly thereafter. *Id.* ¶¶ 44, 45.

As provided for by the applicable statutory regime, Unimed and Besins filed patent infringement suits against Respondents Watson and Paddock in August 2003 in the United States District Court for the Northern District of Georgia. FTC Complaint ¶ 47; Pet. App. 41a-42a. Respondents Watson and Paddock both denied infringement and alleged that the '894 Patent was invalid and/or unenforceable.[4] FTC Complaint ¶¶ 3, 88-89. From late 2003 to the middle of 2005, the parties engaged in discovery, scheduling, and other initial litigation matters. Pet. App. 42a. By the end of 2005, the parties had filed claim construction briefs, and Watson and Par/Paddock had filed motions for partial summary

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[3] As the first ANDA filer, Watson was eligible for the 180-day marketing exclusivity for its proposed generic AndroGel product. FTC Complaint ¶ 45. Watson relinquished its claim to the 180-day marketing exclusivity as part of the patent litigation settlement challenged by the FTC in this case. *See* Pet. App. 49a.

[4] During the litigation, Respondent Paddock partnered with Par Pharmaceutical Companies, Inc. ("Par"), another generic drug company, in order to share litigation costs. FTC Complaint ¶¶ 2, 46. Par and Paddock are hereinafter referred to as "Par/Paddock."

judgment on specific issues. FTC Complaint ¶ 90; Pet. App. 42a-43a. Notably, the partial summary judgment motions that Watson and Par/Paddock did file would not have been case-dispositive even if Watson and Par/Paddock had prevailed on all of the pending issues. Br. for Appellees Unimed Pharm., Inc., Abbott Products, Inc., and Watson Pharm., Inc., at 10, *FTC* v. *Watson Pharm., Inc.*, Case No. 10-12729-DD (11th Cir. filed Nov. 10, 2010).

In January 2006, the 30-month stay of final approval of Watson's ANDA expired; at that point, and upon receiving final FDA approval, Watson legally could have launched its generic drug even though the infringement lawsuit against it was still in progress. FTC Complaint ¶¶ 47, 52. Such a launch is commonly referred to as an "at-risk launch." Had Watson launched but ultimately lost the infringement action, it would have been liable for significant damages. Watson did not launch its generic drug "at risk" in January 2006 or at any time thereafter. *Id.* ¶ 65.

In September 2006, the parties settled both cases prior to any decision on claim construction or on the pending partial summary judgment motions. FTC Complaint ¶¶ 65, 76; Pet. App. 12a, 43a. Unimed and Watson filed a voluntary stipulation of dismissal terminating the suit against Watson, and Unimed's suit against Par/Paddock was dismissed under a consent judgment filed by the parties. FTC Complaint ¶¶ 68, 80. The terms of both settlements reflected an agreement to dismiss the patent cases, as well as the grant of licenses to Respondents Watson and Par/Paddock to launch their respective generic 1% testosterone gels in August 2015 — in other words,

five years prior to expiration of the '894 patent. *Id.* ¶¶ 65, 76; Pet. App. 43a-44a.

In business deals concluded at the same time as the settlement agreements, Respondent Watson agreed that its sales force would promote AndroGel to urologists. FTC Complaint ¶ 66. In return, Respondent Solvay agreed to pay Watson a portion of the profits generated by the sale of AndroGel to urologists. *Id.* ¶¶ 64, 66. The FTC Complaint alleged that Solvay anticipated that Watson's portion of the profits under this contract would amount to approximately $20-30 million annually. *Id.* ¶ 66. As for Par/Paddock, Par agreed that its sales force would promote AndroGel to primary care physicians from 2006 until 2012, and Solvay agreed to pay Par $10 million annually for these promotion services. *Id.* ¶ 77. Paddock was to provide backup manufacturing capacity for AndroGel from 2006 until 2012, and Solvay agreed to pay Paddock $2 million annually for this backup capacity. *Id.* The FTC Complaint alleged that these business deals were not independent business transactions and that Solvay's payments exceeded the value of services provided. *Id.* ¶¶ 82, 84.

3. Shortly after the settlement of the patent litigations, in late 2006, the FTC initiated an investigation into whether Respondents Solvay, Watson, and Par/Paddock had committed antitrust violations by entering into the settlement agreements and business arrangements. *See* Pet. App. 45a. The FTC's investigation continued for over two years, during which extensive discovery was taken.

4. On January 27, 2009, the FTC filed suit in the United States District Court for the Central District of California, challenging the two patent settlements

under the antitrust laws. Respondents' motion to transfer venue pursuant to 28 U.S.C. § 1404(a) was granted by the California district court, and the cases were transferred to the Northern District of Georgia, where the underlying patent cases had been litigated. *See FTC* v. *Watson Pharm., Inc.*, 611 F. Supp. 2d 1081 (C.D. Cal. 2009). Once in Georgia, this case, as well as coordinated cases brought by private plaintiffs, were assigned to Judge Thomas W. Thrash, Jr. — the same judge who had presided over the underlying patent lawsuits between Respondents Solvay, Watson, and Par/Paddock.

The FTC Complaint alleged that the settlements were unfair methods of competition in violation of section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a)(1). It sought declaratory relief, as well as injunctive relief preventing the defendants from engaging in unspecified "similar" and "related" conduct. *See* FTC Complaint, Prayer for Relief.

Respondents moved to dismiss the FTC Complaint. On February 22, 2010, the district court dismissed the FTC's claims, relying on the Eleventh Circuit's decisions in *Schering-Plough Corp.* v. *FTC*, 402 F.3d 1056 (11th Cir. 2005), *Andrx Pharmaceuticals, Inc.* v. *Elan Corp. PLC*, 421 F.3d 1227 (11th Cir. 2005), and *Valley Drug Co.* v. *Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003). Pet. App. 47a-52a. The district court recognized that, in evaluating an antitrust challenge to a Hatch-Waxman patent settlement, Eleventh Circuit precedent required consideration of "(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects." *Id.* at 48a (quoting

Schering, 402 F.3d at 1066) (internal quotation mark omitted). The district court found that the settlements did not exceed the scope of the patent's exclusionary potential given the lack of any allegation that the settlement agreements "exclude[d] any product other than generic AndroGel," and the fact that the settlements in fact "provide[d] for five years less exclusion than the '894 patent." Pet. App. 48a-49a. Because the FTC had "not allege[d] that the settlements exceed the scope of the '894 patent," pursuant to *Valley Drug* and *Schering-Plough* the district court ruled that "it [did] not matter if the Defendants settled their patent disputes with reverse payments." *Id.* at 52a. The district court dismissed the FTC Complaint in its entirety and the FTC did not seek leave to amend.[5]

5. The Court of Appeals affirmed. Pet. App. 1a-36a. Rejecting the FTC's arguments that reverse-payment settlements should be presumptively unlawful restraints of trade, the court hewed to the rule established in *Valley Drug*, *Schering-Plough*, and *Andrx*. Accordingly, "absent sham litigation or fraud

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[5] With regard to antitrust litigation by private plaintiffs regarding the same agreements at issue here, the district court permitted the cases to proceed because, unlike the FTC, those plaintiffs alleged that the underlying patent litigation was sham litigation. Pet. App. 57a. The district court recently granted summary judgment in defendants' favor on the sham litigation claims after finding that the positions Unimed took in the underlying patent litigation were not objectively baseless within the meaning of *Professional Real Estate Investors, Inc.* v. *Columbia Pictures Industries, Inc.*, 508 U.S. 49 (1993). *See In re AndroGel Antitrust Litig.*, 2012 WL 5352986 (N.D. Ga. Oct. 30, 2012). Appeals from that decision have been docketed. *See, e.g.*, *Meijer Inc.* v. *Unimed Pharm. Inc., et al.*, Case No. 12-15562-B (11th Cir. docketed Oct. 30, 2012).

in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." *Id.* at 4a, 28a.[6]

The Court of Appeals further rejected the FTC's argument that Eleventh Circuit precedent should be interpreted to find a "reverse-payment" settlement to be unlawful "'if, viewing the situation objectively as of the time of settlement, it is more likely than not that the patent would not have blocked generic entry earlier than the agreed-upon entry date.'" *Id.* at 29a. Emphasizing that its decisions "focus on the potential exclusionary effect of the patent, not the likely exclusionary effect," the court noted that the FTC's suggested approach would require an "after-the-fact calculation of how 'likely' a patent holder was to succeed in a settled lawsuit if it had not been settled." *Id.* at 30a, 32a. Such a "retroactive[] predicti[on] from a past perspective [of] a future that never occurred," the court said, was "too perilous an enterprise to serve as a basis for antitrust liability and treble damages," and would "impose heavy burdens on the parties and the courts." *Id.* at 32a, 33a. Concerned that our legal system "can ill afford" an approach that would require mining through "mountains of evidence" to assay the infringement claim, thereby "undo[ing] much of the benefit of settling patent litigation" and "discourag[ing] settlements," the

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[6] As defined by the Court of Appeals, a so-called "reverse-payment" settlement is a settlement where "a patent holder pays the allegedly infringing generic drug company to delay entering the market until a specified date, thereby protecting the patent monopoly against a judgment that the patent is invalid or would not be infringed by the generic competitor." Pet. App. 3a.

Court of Appeals declined the FTC's invitation to "attempt to decide how some other court in some other case at some other time was likely to have resolved some other claim if it had been pursued to judgment." *Id.* at 33a, 36a.

The Court of Appeals denied rehearing en banc, *Id.* at 62a-63a, and this Petition followed.

REASONS FOR GRANTING THE WRIT

This Court should grant a writ of certiorari to resolve this recurring question of national importance. As the Petition points out, the U.S. pharmaceutical industry, which brings many life-saving brand-name drugs and generic equivalents to market each year, is a multi-billion-dollar industry. Pet. 16. The Petition also acknowledges that the likelihood of patent infringement litigation inheres in the statutory and regulatory framework for generic drug approval (*id.* at 4) — indeed, as this Court has recognized, the relevant framework "provok[es] litigation." *Caraco*, 132 S. Ct. at 1677. Once embroiled in expensive and lengthy patent litigation, the litigating parties must know on what terms they may settle, or otherwise face treble-damages exposure from antitrust claims brought years later by unrelated third parties who allege that the patent litigation might have ended quite differently if litigated to conclusion.

Prior to July 2012, the courts of appeals were in agreement that the "scope of the patent" test, reaffirmed by the court below, was the appropriate mode of antitrust analysis for Hatch-Waxman patent litigation settlements. Under the "scope of the patent" test, a final settlement of *bona fide* litigation to enforce a non-fraudulently obtained patent is immune

from antitrust attack so long as its alleged exclusionary effects fall within the exclusionary potential of the patent, regardless of whether the settlement is accompanied by consideration to the generic manufacturer. The recent decision by the Court of Appeals for the Third Circuit expressly rejected this previous consensus in adopting the notion that reverse-payment settlements are presumptively unlawful. The Government now urges the Court to reject the clear and tested "scope of the patent" rule, reverse the court below, and instead adopt the ambiguous, incorrect, and burdensome rule announced by the Third Circuit.

For the reasons set out below, the Court should grant the Petition in order to resolve this intractable split and restore certainty to the antitrust analysis of pharmaceutical patent litigation settlements.

I. There is a Direct and Acknowledged Split in the Circuits.

At the time the Court of Appeals issued its decision reaffirming the "scope of the patent" rule, three courts of appeals had expressly agreed that this rule correctly balanced the intellectual property rights of patent holders with the pro-competitive tenets of the antitrust laws. *See* Pet. App. 1a-36a; *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005), *amended*, 466 F.3d 187 (2d Cir. 2006), *cert. denied*, 551 U.S. 1144 (2007); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) ("*Cipro*"), *cert. denied*, 129 S. Ct. 2828 (2009).[7]

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[7] As the Government notes, the Sixth Circuit and the District of Columbia Circuit have not expressly adopted a specific standard for analyzing Hatch-Waxman patent settlements. Pet.

This clear line of case law was disrupted by the recent decision of the Court of Appeals for the Third Circuit in *In re K-Dur Antitrust Litigation*, 686 F.3d 197 (3d Cir. 2012), *petitions for cert. pending*, No. 12-245 (filed Aug. 24, 2012) ("Merck Petition") and No. 12-265 (filed Aug. 29, 2012) ("Upsher-Smith Petition"). Faced with a patent litigation settlement, the Third Circuit expressly rejected the approach taken by the Eleventh, Second, and Federal Circuits. *Id.* at 218 ("we reject the scope of the patent test"). Instead, the Third Circuit announced its own rule in which patent litigation settlements involving a payment are presumptively unlawful under the antitrust laws. The Third Circuit directed the finder of fact to "treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade," which could be rebutted "by showing that

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13 (citing *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003) and *Andrx Pharm., Inc.* v. *Biovail Corp. Int'l.*, 256 F.3d 799 (D.C. Cir. 2001)). Notably, the United States, in an amicus brief to this Court in which it was joined by the FTC, has interpreted *Cardizem* as concerning an agreement that was clearly beyond the exclusionary potential of the patent at issue. *See* Br. for the United States as *Amicus Curiae*, 2004 WL 1562075, at *13, *Andrx Pharm., Inc.* v. *Kroger Co.*, 543 U.S. 939 (July 9, 2004) (No. 03-779), (arguing that *Cardizem* is "better read . . . as limited to the particular agreement before the court," which "extend[ed] beyond the legitimate scope of the patent claims"). *Andrx* v. *Biovail* concerned the same agreement, and focused on the alleged harm flowing from the first-filing generic manufacturer's agreement to "continue to prosecute its ANDA" and to exclude others by "do[ing] nothing to jeopardize its 180-day exclusivity." *Andrx* v. *Biovail*, 256 F.3d at 814; *see also id.* at 808-11.

the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit." *Id.*

This case, therefore, undeniably implicates a square split among the courts of appeals.

II. The Petition Presents an Important Issue, and the Split Should Be Resolved By this Court.

Given the size and importance of the pharmaceutical industry, and the fact that patent litigation regularly arises in the approval process for generic drugs, clear guidance from this Court is warranted now on the appropriate antitrust analysis of settlements of Hatch-Waxman patent litigation. In light of the likely impact of the Third Circuit's erroneous decision on the pharmaceutical industry, further percolation of this issue through the courts will not be meaningful.

A. A National Rule Establishing the Correct Antitrust Analysis of Patent Settlements is of Paramount Importance.

1. The uncertainty created by the circuit split will have profound effects within the pharmaceutical industry. As noted above, patent infringement litigation is very likely in the process to obtain approval for a Paragraph IV ANDA (the only type of ANDA for which generic entry prior to expiration of an Orange Book-listed patent is a possibility). Any generic pharmaceutical company contemplating the filing of a Paragraph IV ANDA must know *prior to filing*, *i.e.*, well in advance of any lawsuit against it, the rule of law applicable to any potential litigation. Moreover, fairness dictates that litigating parties who are considering settlement of Hatch-Waxman

patent litigation ought to be able to gauge at the time of settlement whether their agreement comports with the antitrust laws.

The "scope of the patent" rule, reaffirmed by the court below, provides precisely this type of clarity. So long as the terms of the settlement do not exceed the patent's exclusionary potential, the parties may settle their dispute and, in many cases, allow for generic entry earlier than patent expiration. This rule had been followed by the courts of appeals consistently since *Valley Drug* in 2003. *See Valley Drug*, *supra*; *Schering-Plough*, *supra*; *Tamoxifen*, *supra*; *Cipro*, *supra*; *Ark. Carpenters Health & Welfare Fund* v. *Bayer AG*, 604 F.3d 98 (2d Cir. 2010), *cert. denied*, 131 S.Ct. 1606 (2011); Pet. App. 1a-36a.

The rule endorsed by the Third Circuit and in the Government's Petition[8] leaves litigants the "choice" of settling with some consideration to the generic company and facing the very real risk of treble-damage antitrust liability, or litigating to the bitter end. Neither law nor logic supports creation of this Hobson's choice, nor is it sound policy.

The Third Circuit's statement that its rule of presumptive illegality does not extend to settlements based only on a negotiated entry date for the marketing of the generic drug (known as "entry-date-only" settlements) fails to ameliorate this problem. *K-Dur*,

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[8] As the Government acknowledges, in the proceedings before the Court of Appeals, the FTC actually suggested two possible approaches to analyzing the legality of Hatch-Waxman patent settlements: (i) the "more likely than not" test that the FTC argued was consistent with Eleventh Circuit precedent (Pet. 8); and (ii) the presumptively unlawful/*K-Dur* test it endorses now. *Id.* at 10.

686 F.3d at 217-18. As numerous commentators, including the FTC's current General Counsel, have explained, an entry-date-only settlement frequently is not possible where the parties have varying risk tolerances or where information asymmetries exist. *See, e.g.*, Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements*, 15 Fed. Cir. B. J. 617, 619, 628-31(2005) ("there are a number of reasons why such a [simple split of the patent term] may not be available," including "asymmetric time horizons and asymmetric risk profiles or expectations"; if the parties have asymmetric expectations about litigation success, "[a] cash payment can bridge that gap."); *see also* Bret Dickey, Jonathan Orszag, & Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 Ann. Health Law 367, 391 (2010) ("Under certain conditions, without the bargaining tool of a payment from the brand-name manufacturer to the generic manufacturer, the parties will be unable to reach agreement on a settlement, even if that settlement would benefit consumers.").

2. Where the choice faced by the settling parties is either risking subsequent antitrust liability or maintaining prolonged litigation to final judgment, the long-term result is likely to be fewer Paragraph IV ANDA challenges overall. For generic pharmaceutical companies, Paragraph IV litigation requires a substantial commitment of resources, and this commitment of resources must be considered in the earliest stages of development of any given generic drug; in other words, well in advance of any ANDA filing. If, unlike in other litigation, there is no meaningful settlement option and the only possibility is a

drawn-out, expensive, uncertain litigation to final judgment, generic pharmaceutical companies may well decide, in the face of potentially catastrophic treble damages exposure and exorbitant litigation costs, not to file Paragraph IV ANDAs. *See Asahi Glass Co., Ltd.* v. *Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) ("A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive."); *see also* Br. of *Amicus Curiae* Generic Pharm. Ass'n at 9-14, *Upsher-Smith Labs., Inc.* v. *La. Wholesale Drug Co.*, Case No. 12-265 (filed Oct. 1, 2012). The aggregate effect of fewer challenges and fewer settlements may well mean that consumers in the long run have less — and delayed — access to generic drugs, a result contrary to the goals that the FTC generally aims to promote.

The Government's Petition, and the Third Circuit rule, disregard entirely these long-term systemic effects that would have a tremendously detrimental impact on the availability of generic alternatives in the marketplace.

B. Further Percolation in the Courts Will Only Exacerbate the Problem.

Further percolation of the issue will not be meaningful, and, as the Government acknowledges, will only lead to forum shopping. Pet. 15. The fact that only one Court of Appeals has adopted a divergent test is not cause to deny the Petition; rather, in this case, it underscores the urgency for a clear rule.

The FTC's Chairman has already announced publicly that so long as the Third Circuit's *K-Dur* decision stands, the FTC will bring all of its "reverse-payment" cases in the Third Circuit. *See* Jon Leibowitz, FTC Chairman, Remarks at Sixth Ann. Georgetown L. Global Antitrust Enforcement Symposium 4 (Sept. 19, 2012), http://www.ftc.gov/speeches/leibowitz/120919jdlgeorgetownspeech.pdf (last visited Nov. 7, 2012). The Petition, moreover, acknowledges that the FTC will no longer use administrative proceedings to challenge "reverse-payment" settlements because they might be subject to review outside of the Third Circuit. Pet. 15 (the adoption of the "scope of the patent" rule by numerous courts of appeal has "effectively disabled the FTC from proceeding administratively against any reverse-payment agreement" because a Commission decision finding a reverse-payment agreement unlawful could be appealed to courts besides the Third Circuit).

In addition, many of the nation's pharmaceutical companies, including Respondent Watson, are headquartered in the Third Circuit. If the circuit split is permitted to stand, there exists a high probability that many, if not most, cases challenging reverse-payment settlements as unlawful will simply be brought there. For these reasons, this single, erroneous appellate decision will have an outsized effect on the pharmaceutical industry.

III. The Rule Adopted By the Eleventh, Second, and Federal Circuits is Correct, and the Third Circuit's Rule is Erroneous.

The "scope of the patent" rule is consistent with this Court's precedents and with the judicial policy that settlement of disputes is to be encouraged. In

contrast, the Government's proposed "presumptively unlawful" rule — which effectively classifies settlements of Hatch-Waxman patent litigation that include a payment as naked restraints of trade — is inconsistent with this Court's precedents, fails properly to account for intellectual property rights, disregards the fact that such settlements are often pro-competitive, and is premised upon economic analysis and data that are far from sufficient to support the Government's sweeping approach.

A. Contrary to the Government's position, the Eleventh Circuit Rule is Plainly Correct.

The rule reaffirmed by the court below, and followed by the Second and Federal Circuits, reflects the appropriate evaluation of the exclusionary rights of patent holders and the antitrust laws. The analysis of the court below correctly took the existence of the patent — granted by the USPTO and entitled to a presumption of validity, 35 U.S.C. § 282 — as its point of departure. Under this Court's longstanding precedents, the scope of the patent forms the zone within which the patent holder may operate without facing the specter of antitrust liability. *See, e.g.*, *U.S.* v. *Line Materials Co.*, 333 U.S. 287, 300 (1948) ("[T]he precise terms of the grant define the limits of a patentee's monopoly and the area in which the patentee is freed from competition of price, service, quality or otherwise."); *U.S.* v. *Gen. Elec. Co.*, 272 U.S. 476, 485, 489 (1926) ("it is only when . . . [the patentee] steps out of the scope of his patent rights" that he comes within the operation of the Sherman Act).

Moreover, the scope of the patent rule is consistent with the general judicial policy and rule of law favoring settlement. The court below recognized the immense burden that a relitigation of the patent merits — inherent in the Government's suggested approach (*see infra* III.C.) — would impose upon litigants and the courts, something our legal system "can ill afford." Pet. App. 33a (collecting cases emphasizing the importance of settlement to our judicial system).

B. The Government's Characterization of Patent Litigation Settlements is Erroneous.

By advocating a "presumptively unlawful" standard, the Government endorses an approach whereby an antitrust plaintiff can make out a *prima facie* case for an antitrust violation without any affirmative proof of anticompetitive effect, and where there is in fact no consensus that there is such an effect. Although the Petition nominally characterizes the "presumptively unlawful" test as a "rule of reason" approach (as did the Third Circuit in *K-Dur*), the Petition places reverse-payment settlements on par with naked restraints on trade. Pet. 11, 22 ("the federal antitrust laws flatly prohibit potential competitors from forming naked agreements not to compete"); *id.* at 26 (reverse-payment settlements are "collusive agreements").

Ordinarily, restraints are not considered to be naked restraints subject to *per se* condemnation until courts have had sufficient experience with the restraints to know that the anticompetitive effects are obvious. *See Bus. Elecs. Corp.* v. *Sharp Elecs. Corp.*, 485 U.S. 717, 723 (1988) ("*per se* rules are appropri-

ate only for 'conduct that is manifestly anticompetitive,'" that is, conduct "that would always or almost always tend to restrict competition and decrease output") (internal citation omitted); *State Oil Co.* v. *Khan*, 522 U.S. 3, 10 (1997) ("[W]e have expressed reluctance to adopt per se rules with regard to restraints imposed in the context of business relationships where the economic impact of certain practices is not immediately obvious.") (internal quotation marks omitted). Contrary to this established authority, the rule endorsed by the Government and the Third Circuit finds agreements presumptively unlawful without sufficient judicial experience or economic justification demonstrating that the agreements are, in fact, pernicious. *Cf. Cal. Dental Ass'n* v. *FTC*, 526 U.S. 756, 770 (1999) ("quick-look analysis carries the day when the great likelihood of anticompetitive effects can easily be ascertained").

In urging the Court to accept a rule that equates "reverse-payment" settlements with naked restraints of trade, the Government inappropriately assumes away a patent holder's intellectual property rights. *See, e.g.*, Pet. I (taking as its point of departure the premise that a patent holder only "assertedly" holds a patent). Such a disregard for the rights of the patentee overlooks established precedent holding that so long as the patent holder operates within the scope of its patent's protections, there is no restraint of trade beyond that which is statutorily granted. *See U.S.* v. *Gen. Elec. Co.*, *supra*; *Dawson Chem. Co.* v. *Rohm & Haas Co.*, 448 U.S. 176, 215 (1980) (a patent grants the patent holder the lawful "right to exclude others from profiting by the patented invention"); *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1327 (Fed. Cir. 2000), *cert. denied*, 531 U.S. 1143

(2001) ("[I]n the absence of any indication of illegal tying, fraud in the Patent and Trademark Office, or sham litigation, the patent holder may enforce the statutory right to exclude others from making, using, or selling the claimed invention free from liability under the antitrust laws."); *cf. U.S.* v. *Masonite Corp.*, 316 U.S. 265 (1942). Moreover, "[i]t is inappropriate to use an analytical model in which the benefits of price competition on one side of the equation are taken into account, but the benefits of innovation on the other side of the equation are not." Bernard & Tom at 621.

Perhaps most importantly, however, such a characterization is inappropriate in light of the broad recognition, *including by the Government and the FTC in a brief filed with this Court*, that patent litigation settlements with payments are often procompetitive. *See, e.g.*, Br. for the United States as Amicus Curiae at *12, *Andrx* v. *Kroger* ("Certain settlements of patent litigation may benefit consumers and the public, regardless of the presence of a payment to the alleged infringer, and thus application of a per se rule would be inappropriate."); Bernard & Tom at 622 ("if the settlement prevents infringing entry, such prevention is itself a *pro-competitive* effect"); Dickey, Orszag, and Tyson at 368 (article demonstrates "that patent settlements between branded and generic pharmaceutical manufacturers, including those that involve reverse payments, . . . can benefit consumers."); *see also* Bret Dickey, Jonathan Orszag, & Robert Willig, *A Preliminary Economic Analysis of the Budgetary Effects of Proposed Restrictions on "Reverse-Payment" Settlements*, at 3-4 (Aug. 10, 2010), http://www.compasslexecon.com/highlights/Document

s/Dickey%20Orszag%20Willig%20CBO.pdf (last visited Nov. 7, 2012) (discussing how "reverse-payment" settlements can lead to lower drug costs).

Finally, there is evidence that the statistics underpinning the Government's allegations as to the "delay" supposedly achieved through "reverse-payment" settlements are far from adequate to justify the Government's sweeping position. For example, the Government relies on decade-old statistics in asserting that "generic competitors have prevailed three quarters of the time in paragraph IV patent litigation against brand-name manufacturers." Pet. 18. Yet a more recent study found a far lower success rate for the generic drug industry. *See* Adam Greene & D. Dewey Steadman, *Analyzing Litigation Success Rates*, RBC Capital Markets, at 4 (January 15, 2010), http://www.amlawdaily.typepad.com/pharmareport.pdf (last visited Nov. 8, 2012) ("the overall success rate for the generic [drug] industry is 48%"). Economists have also questioned the FTC's statistic that the average "delay" of generic entry following settlement with a "reverse-payment" was 17 months. *Compare* Pet. 20 *and* Dickey, Orszag, & Willig at 3 ("there is no sound rationale for assuming that the inclusion of a payment from the branded to the generic manufacturer as part of the settlement agreement *caused* the observed differences in entry dates by the generic manufacturers."). Moreover, the FTC's study does not account for the true "but-for" world, including how many generic challenges would otherwise have been filed, or whether the litigation outcomes would have been different if those more uncertain cases had been forced to trial.

The foregoing factors demonstrate fundamental flaws in the Government's suggestion that "reverse-payment" patent settlements properly belong in the category of presumptively unlawful restraints.

C. In Endorsing the Third Circuit Rule, the Government's Analysis of the Antitrust Issue is Erroneous.

Antitrust law does not prohibit settlements of litigation by competitors as such; it is only those agreements that unreasonably restrain trade that concern the antitrust laws. *See Khan*, 522 U.S. at 10. In an antitrust case, it is ordinarily the plaintiff's burden to show that the challenged agreement has a substantial anticompetitive effect. *See U.S.* v. *Arnold Schwinn & Co.*, 388 U.S. 365, 374 n.5 (1967) ("The burden of proof in antitrust cases remains with the plaintiff, deriving such help as may be available in the circumstances from particularized rules articulated by law – such as the per se doctrine."), *overruled on other grounds by Cont'l T.V., Inc.* v. *GTE Sylvania, Inc.*, 433 U.S. 36, 58-59 (1977).

Here, the Government proposes a rule whereby its *prima facie* case is stated upon (i) the allegation of the existence of a patent settlement agreement between a brand-name manufacturer and a generic manufacturer; and (ii) the allegation that a "payment" was made to the generic manufacturer. Pet. 13, 22. As a preliminary matter, the ambiguity in the word "payment" is problematic, given that in the Government's view, the "payment" serves as the trigger for potential antitrust liability. *See Id.* at 13 ("any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market [is] *prima facie* evidence of an unreasonable

restraint of trade"). The Government clearly interprets this rule broadly to include not only naked cash payments, but also alleged overpayment for business deals (even where the brand-name manufacturer is concededly receiving actual services in exchange for that "payment", *see* FTC Complaint ¶¶ 66, 82). Indeed, the FTC urged the Court of Appeals to adopt its burden-shifting approach "whenever the patent holder provides economic value to the challenger *in any form* in connection with delayed entry," Pet. of Fed. Trade Comm'n for Rehr'g En Banc at 13, *FTC v. Watson Pharm., Inc.*, Case No. 10-12729 (11th Cir. filed June 11, 2012) (emphasis added), and has urged in other courts that "payment" under the *K-Dur* test should include non-cash consideration in the form of an agreement by the brand-name manufacturer not to launch an authorized generic product during the first-filing generic manufacturer's 180-day exclusivity. *See* Br. of the Fed. Trade Comm'n as *Amicus Curiae* at 1-2, *In re Lamictal Direct Purchaser Antitrust Litig.*, Doc. No. 89-3, Case No. 2:12-cv-00995-WHW-MCA (D.N.J. filed Oct. 5, 2012).[9]

Perhaps more troublesome, however, is that the "presumptively unlawful" test frees the plaintiff entirely from having to prove the anticompetitive nature of the alleged restraint. By presuming delay, this test shifts the burden to the defendants to prove the negative, *i.e.*, that their settlement agreement is *not* anticompetitive. Pet. 13 (once a *prima facie* case

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[9] An "authorized generic" is a drug that is chemically identical to the brand-name drug, but is sold as a generic product under the same FDA approval as the brand-name drug. *See* Br. of Fed. Trade Comm'n as *Amicus Curiae* at 5, *In re Lamictal Direct Purchaser Antitrust Litig.*

is made out, the settling parties must prove either "'that there is in fact no reverse payment because any money that changed hands was for something other than a delay,'" or "'that the reverse payment offers a competitive benefit that could not have been achieved in the absence of a reverse payment.'"). Inherent in the presumption of "delay," however, is the presumption that the underlying litigation would have ended some other way; to exonerate itself, an antitrust defendant would necessarily have to relitigate the patent merits in order to show what the "true" entry date would have been had the case been litigated to conclusion.[10] This Court should be wary of a test that requires courts to "attempt to decide how some other court in some other case at some other time was likely to have resolved some other claim if it had been pursued to judgment." Pet. App. 36a. This would be the "turducken task" that the court below correctly recognized as inherently unreliable (*Id.* at 33a, 36a), an inappropriate drain on party and judicial resources (*id.* at 33a), and contrary to the judicial policy favoring settlement. *Id.*

For all these reasons, the "scope of the patent" rule as articulated by the Eleventh Circuit is the correct rule for analyzing the legality of Hatch-Waxman patent settlements under the antitrust laws.

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[10] As observed by the California district court in which the FTC originally filed this case, while the FTC "still [took] the position under the per se theory that 'these [reverse payment] agreements are flat out illegal,'" the FTC "admitted in the hearing before this Court that it could not litigate this case without also including a theory of competitive harm that would necessitate looking to the merits of the patent cases." *FTC* v. *Watson*, 611 F. Supp. 2d at 1088 (citing Tr. of Mot. to Transfer Hr'g at 35-39).

IV. This Case Presents A Compelling Vehicle For The Court's Consideration of This Issue.

This case comes to the Court on a clean record, as an appeal of a final judgment dismissing the FTC Complaint, with the issue crisply presented. The dispute is contained within the four corners of the FTC Complaint. As the district court and the Court of Appeals recognized, the FTC Complaint does not allege that the challenged settlements exceeded the scope of the exclusionary potential of the patent. *See* Pet. App. 48a (emphasizing that the FTC did "not allege that the settlements . . . exceed the scope of the '894 Patent"); Pet. App. 29a, n.10 ("[the FTC's Complaint] does not contend that any of the three companies knew the patent was invalid or not infringed or that there was no objective basis to believe the patent was valid and infringed.").

As the Government points out, unlike the *K-Dur* case, for which two petitions for certiorari are pending (*see* Merck and Upsher-Smith Petitions), the present case is devoid of factual issues that could bog down a clear resolution of this important question and comes to this Court on a motion to dismiss. Pet. 30. In contrast, *K-Dur* comes to this Court on an extensive summary judgment record. Moreover, the *K-Dur* case represents an interlocutory appeal; this case, in contrast, presents a final judgment, and no additional issues remain.

For the reasons stated above, the Court should grant the Government's Petition. In the alternative, the Court may wish to grant the Petition in tandem with the pending petitions in *K-Dur*, and provide additional time for oral argument.

CONCLUSION

For the foregoing reasons, the Court should grant the petition for a writ of certiorari.

Respectfully submitted,

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REPLY BRIEF

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In the Supreme Court of the United States

FEDERAL TRADE COMMISSION, PETITIONER

v.

ACTAVIS, INC., ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

REPLY BRIEF FOR THE PETITIONER

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ACTAVIS, INC., ET AL.

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REPLY BRIEF FOR THE PETITIONER

A. The "Quick Look" Approach Identifies And Condemns Collusive Behavior That Destroys The Competitive Relationship Between Drug Manufacturers

1. The antitrust rule of reason—which even respondents profess to apply—must "take into account * * * 'specific information about the relevant business' and 'the [challenged] restraint's history, nature, and effect.'" *Leegin Creative Leather Prods., Inc.* v. *PSKS, Inc.*, 551 U.S. 877, 885 (2007) (citation omitted); see *United States* v. *American Tobacco Co.*, 221 U.S. 106, 179 (1911) (looking to the "inherent nature or effect" and "evident purpose" of a restraint). If a particular restraint "give[s] rise to an intuitively obvious inference of anticompetitive effect," a court should "place the burden of procompetitive justification on those who agree [to the restraint]." *California Dental Ass'n* v. *FTC*, 526 U.S. 756, 781, 771 (1999).

As the government's opening brief explains (Br. 8-9, 21-24), the practical economics of paragraph IV litigation in the pharmaceutical industry are these: When parties to paragraph IV litigation settle a case by simply agreeing on a compromise date of generic entry, the generic manufacturer's incentive is to negotiate the earliest possible entry date to maximize its own profits. That incentive ensures that consumer interests will receive significant protection in the negotiating process, and it provides reason for confidence that the agreed-upon entry date reflects the parties' own assessment of the likely litigation outcome. By contrast, a Hatch-Waxman settlement that includes a reverse payment allows the brand-name manufacturer to co-opt its rival by sharing the monopoly profits that result from an artificially prolonged period of market exclusivity. That result maximizes the manufacturers' profits at consumers' expense.

Respondents and their amici do not dispute those basic economic realities, which bear an unmistakable resemblance to those surrounding other payments not to compete. See *Palmer* v. *BRG of Ga., Inc.*, 498 U.S. 46, 49-50 (1990) (per curiam); Pet. Br. 20. Respondents and their amici similarly do not dispute that a plaintiff's making large cash payments to a defendant—here, tens of millions of dollars—is an extraordinary and peculiar way to settle a lawsuit. Such a payment from a patentee to an accused infringer provides the defendant an important economic benefit that it could not hope to obtain even by prevailing in the litigation, and it has no apparent analogue in traditional settlement practice. Taken together, those circumstances warrant "a confident conclusion" that "the principal tendency" (*California Dental*, 526 U.S. at 781) of a reverse-payment agree-

ment is anticompetitive, so that the burden of identifying a procompetitive justification is properly placed on the agreeing parties.

2. Respondents' efforts to distinguish reverse-payment settlements from other agreements not to compete are unpersuasive.

a. Respondents suggest that reverse-payment agreements should be regarded as procompetitive because they can provide for generic competition before the patent expires (*i.e.*, before generic entry would have been permitted if the brand-name manufacturer had won the lawsuit). See, *e.g.*, Solvay Br. 26-27. In this case, for example, the agreements allowed generic entry in 2015, while the relevant patent was scheduled to expire in 2020. Under respondents' own theory, however, the presence or absence of such procompetitive potential is irrelevant to the proper antitrust analysis. Absent sham litigation or fraud on the PTO, the scope-of-the-patent rule would treat as legitimate a settlement under which the generic manufacturer agreed to defer entry until the date of patent expiration—*i.e.*, accepted the least amount of generic competition that could result from judicial disposition of the infringement suit—in return for a substantial cash payment. See Pet. Br. 43 n.10.

By definition, moreover, reverse-payment settlements of paragraph IV litigation are agreements between competitors who have previously taken conflicting positions as to the proper disposition of the infringement suit. Such suits are triggered by the generic manufacturer's paragraph IV certification that the relevant patent is invalid and/or not infringed. Although the respondents in this case agreed to a generic entry date earlier than the date of patent expiration, the agreed-

upon date was considerably later than the date generic competition would have begun if Watson or Par/Paddock had prevailed in its lawsuit. In determining the agreement's effect on competition, there is no logical reason to use as the benchmark the date that generic entry could have occurred if Solvay had won the infringement suit.

To be sure, it would be equally inappropriate to use as the antitrust benchmark the date of entry that would have resulted from judgment for the generic competitor. That approach would unduly constrain the ability of paragraph IV litigants to engage in traditional settlement practices since it would effectively condemn agreements that use compromise dates of generic entry *without* reverse payments. See Pet. Br. 27-28. For different (but equally weighty) reasons, it would likewise be inappropriate for the antitrust court to attempt to determine (and to use as a benchmark) the date when generic entry likely would have occurred if the infringement suit had been litigated to judgment. See *id.* at 53-55.

Thus, rather than effectively presuming that either the brand-name or generic manufacturer would have won the infringement suit, or requiring the antitrust court to assess the likely outcome of that suit, the government's approach focuses on the presence or absence of a settlement term that distorts the integrity of the *process* through which the settlement was negotiated. Because "the antitrust laws were passed for 'the protection of *competition*,'" *Brooke Grp. Ltd.* v. *Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 224 (1993) (citation omitted), the rule of reason condemns not only agreements that in a particular instance are conclusively shown to have raised price or lowered output (the test

respondents suppose), but also "actions that harm the competitive process," *Clamp-All Corp.* v. *Cast Iron Soil Pipe Inst.*, 851 F.2d 478, 486 (1st Cir. 1988) (Breyer, J.), cert. denied, 488 U.S. 1007 (1989). Thus, this Court has condemned restraints because they "impede[d] the ordinary give and take of the marketplace," *National Soc'y of Prof'l Eng'rs* v. *United States*, 435 U.S. 679, 692 (1978) (citation omitted), or because they were "likely enough to disrupt the proper functioning of the price-setting mechanism of the market * * * even absent proof that [they] resulted in higher prices," *FTC* v. *Indiana Fed'n of Dentists*, 476 U.S. 447, 461-462 (1986). Of particular relevance here—where Solvay was facing willing and able would-be generic competitors—"[t]he anti-trust laws are as much violated by the prevention of competition as by its destruction." *United States* v. *Griffith*, 334 U.S 100, 107 (1948); see Pet. Br. 20-21. Reverse-payment agreements raise the central concern of antitrust law: that the competitive process that benefits consumers will be thwarted because a potential competitor finds it most profitable to preserve and share in the rewards of the incumbent firm's monopoly.

b. Respondents identify some economists who conclude that it is possible for a reverse-payment agreement to result in generic entry earlier than the "expected" outcome of the litigation (*i.e.*, a theoretical middle-ground date of generic entry that reflects the relative probabilities of the generic manufacturer prevailing and entering immediately or losing and being excluded until patent expiration). See Solvay Br. 32-33; Actavis Br. 24-25. But there is no reason to believe that sort of early entry is the norm when "a rudimentary understanding of [pharmaceutical] economics," *California Dental*, 526 U.S. at 770, suggests otherwise: Ra-

tional manufacturers would not choose those settlements when it is more profitable for them to agree instead to preserve the brand-name manufacturer's monopoly and share the profits, a point those same economists effectively concede.[1] Moreover, the "quick look" approach permits settling parties to show that their reverse-payment agreement is an exceptional case. Pet. Br. 38-39. And none of the economist amici defends respondents' scope-of-the-patent approach.

c. Respondents argue that, for antitrust purposes, "there are no 'weak' patents" (Par/Paddock Br. 8) and "there is no meaningful way to define [such] categories" (Solvay Br. 30). We agree that the antitrust analysis of a Hatch-Waxman settlement should not turn on a judicial assessment of the strength or scope of the *particular* patent involved in the case. In fashioning an appropriate antitrust rule, however, this Court can and should take account of the facts that some patents are stronger and more encompassing than others; that the patents involved in paragraph IV litigation are not likely to be representative of pharmaceutical patents generally (since such litigation occurs only when a generic manufacturer certifies that the patent is invalid and/or will not be infringed by generic competition); and that the parties' own assessment of patent validity and scope will

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[1] See, *e.g.*, Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements That Settle Patent Litigation*, 49 Antitrust Bull. 655, 657 (2004) ("It is plain that some settlement agreements would profitably perpetuate monopoly, to the harm of social and consumer welfare."); Bret Dickey et al., *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 Ann. Health L. 367, 399 (2010) ("Patent settlements between brand-name and generic pharmaceutical manufacturers can be anticompetitive and should continue to be closely scrutinized.").

affect their litigation behavior, including their choice of settlement terms.

Generic drug manufacturers concentrate their resources on challenging patents that are particularly likely to be held invalid or not infringed by the generic manufacturer's product, a practice that is highly beneficial to competition. See C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. Health Econ. 327, 334-335 (2012) (finding "strong evidence that patent challenges target low quality patents and those that extend market life, as opposed to basic patents"). The frequency with which generic manufacturers have prevailed in fully litigated paragraph IV cases (see Pet. Br. 6-7) suggests, not that a large percentage of all pharmaceutical patents are invalid, but that generic manufacturers have chosen their targets astutely and aimed to develop noninfringing products. When the parties to paragraph IV litigation negotiate settlement terms, moreover, "the patents most likely to be the subject of exclusion payments would be precisely those patents that have the most questionable validity." *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 211 (2d Cir. 2006) (citation omitted), cert. denied, 551 U.S. 1144 (2007). In assessing the anticompetitive potential of reverse-payment agreements, it therefore would be particularly unsound to use as a benchmark the assumption that the patent is both valid and infringed.

B. Respondents And Their Amici Mischaracterize The "Quick Look" Approach And Ignore Important Limits On Its Application

Respondents' principal criticisms of the "quick look" approach consist of mischaracterizations of that approach's operation and assertions that it lacks limiting

principles. Those criticisms are unfounded. The "quick look" approach is a structured application of the rule of reason that affords respondents a full opportunity to advance legitimate justifications for their apparently anticompetitive agreements. It is appropriately applied where, as here, "a confident conclusion about the principal tendency of [the] restriction" at issue may be drawn, *California Dental*, 526 U.S. at 781.

1. Respondents describe the "quick look" approach as "a rule of *per se* illegality." Solvay Br. 1. That is incorrect. Under the government's approach, the use of a reverse payment to settle paragraph IV litigation raises a strong presumptive inference that the generic manufacturer has agreed to delay entry beyond the date that would otherwise reflect the parties' assessment of likely litigation outcomes. The agreeing parties can rebut that presumption, however, by showing that the payment was consideration for something other than delay; that it was commensurate with the brand-name manufacturer's expected litigation savings; or, in rare cases, that unusual business or litigation circumstances supply a procompetitive justification for the agreement.[2]

2. Respondents are likewise wrong in describing the government's approach as "an antitrust analysis for patent litigation settlements that disregards the patent." Actavis Br. 19. Under our approach, the parties

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[2] Par/Paddock's fact-specific arguments—that its agreement with Solvay (1) is immunized by being embodied in a consent decree and (2) was not anticompetitive because it delayed generic competition no more than Solvay's agreement with Watson (Br. 63-68)—could be aired within the "quick look" framework. The FTC explained in district court why those arguments fail (see Dkt. 137, at 31-44), but the lower courts should have the opportunity to pass on those issues in the first instance.

to paragraph IV litigation have broad freedom to settle by agreeing upon a compromise date of generic entry. See Pet. Br. 27-28. Although a potential competitor's agreement not to compete for a defined period would ordinarily be a per se violation of the antitrust laws, see *Palmer*, *supra*, a compromise date of market entry is a natural and generally lawful term of an agreement to settle *patent* litigation. The justification for that settlement term, however, depends on the premise that the compromise date chosen reflects the outcome of arm's-length bargaining in which the generic manufacturer seeks to obtain the earliest entry date that the perceived strength of its litigating position allows. A reverse payment undermines that premise by giving the generic manufacturer an evident incentive to accept an entry date later than it could otherwise achieve. Cf. *Tumey* v. *Ohio*, 273 U.S. 510, 532 (1927) (Due Process Clause was violated where judicial officer had financial incentive to convict).

3. Respondents contend that the government has failed to identify "a workable boundary around what constitutes a 'reverse payment,'" Solvay Br. 43, so that the "quick look" approach would in effect presumptively condemn nearly any settlement of patent litigation. That argument is misconceived.

a. For present purposes, it would suffice to understand "payment" as cash, since that is what Solvay agreed to pay Watson and Par/Paddock. See Complaint ¶¶ 66, 73-74, J.A. 46, 48. More generally, the defining characteristics of a reverse payment are that it (1) is consideration from the patentee that the accused infringer could not obtain by prevailing in the litigation, and (2) allows the patentee to co-opt its rival by sharing monopoly profits that align the accused infringer's in-

terests with the patentee's interest in preserving its monopoly. Thus, the logic of the government's position would extend to a settlement involving non-cash consideration if—but only if—those characteristics are present. See Pet. Br. 36 n.7. That would surely be true of "payment" made in gold bullion; it may be true of other business arrangements that have yet to be fully litigated; and it is decidedly not true of a wide range of ordinary settlement practices.

b. Respondents place particular emphasis on the supposed implications of the government's position for ordinary settlement of traditional patent-infringement suits. In such settlements, the patentee accepts a lower amount of damages for alleged past infringement than it might have been awarded in litigation, and the accused infringer accedes to the patent. Respondents assert that this forgiveness of alleged accrued damages is a "payment" no different from the cash payments from a patentee to accused infringer in a reverse-payment agreement. See Solvay Br. 42-45; Actavis Br. 54-55 (citing *Asahi Glass Co.* v. *Pentech Pharms., Inc.*, 289 F. Supp. 2d 986 (N.D. Ill. 2003), appeal dismissed, 104 Fed. Appx. 178 (7th Cir. 2004)).

Respondents' analogy is flawed. See Pet. Br. 30; Nat'l Ass'n of Chain Drug Stores (NACDS) Amicus Br. 8-9; States Amicus Br. 25-27. When the plaintiff in a suit for monetary relief forgoes a portion of its claimed damages, it provides the defendant part (though not all) of the benefit the defendant would have realized by winning the lawsuit. Such an agreement is analogous to a settlement of paragraph IV litigation in which no payment is exchanged and the parties compromise on a date when the generic will enter the market. In both scenarios, the compromise result falls where one would natu-

rally expect it—between the dispositions that could result from litigated judgments in favor of the plaintiff and defendant respectively. See Pet. Br. 27-28.

Where either of those settlement terms is used, all else being equal, weaker patent infringement claims will lead to settlements with lower damages (or royalties) and shorter periods of exclusion than will stronger infringement claims. In neither instance will the accused infringer predictably have an economic incentive to accede to an agreement that preserves the patentee's monopoly (at the expense of consumers' interests). See Pet. Br. 28. Reverse-payment agreements, by contrast, give the generic manufacturer an economic benefit that it could not obtain even by winning the lawsuit, and they provide an evident incentive for the generic to accept a later entry date than the strength of its bargaining position would otherwise allow it to obtain.[3]

4. Some respondents and amici (Solvay Br. 33-34, 57-59; Actavis Br. 23-26) express concern that adopting the "quick look" approach may frustrate attempts to settle paragraph IV litigation. (Par/Paddock presumably thinks otherwise, because it contends that the pharmaceutical industry's use of reverse-payment agreements is "sharply declining." Par/Paddock Br. in Opp. 13.) Although some additional Hatch-Waxman suits may be litigated to judgment if reverse-payment agreements

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[3] In a $1 million damages action, a settlement under which the defendant agrees to pay the plaintiff $500,000 would be routine; a settlement under which the plaintiff agrees to pay the defendant $500,000 would be extraordinary. To be sure, the plaintiff's willingness to compromise its damages claim and the plaintiff's cash payment could both be described as forms of "consideration" to the defendant. Practicing lawyers would have no difficulty recognizing, however, that the former type of consideration is regularly used to settle litigation while the latter is not.

are deemed presumptively unlawful, that prospect is not a sufficient reason to reject the "quick look" approach.

If this Court agrees with the government that reverse-payment agreements should be disfavored, suits that would otherwise be settled with such agreements can be resolved in either of two ways. In most such cases, the parties can be expected to negotiate alternative settlement terms, agreeing on a compromise date of generic entry, with or without a licensing royalty paid by the generic manufacturer to the patentee.[4] To the extent the "quick look" approach prompts the parties to paragraph IV litigation to settle on those terms, it is an unalloyed good. To induce the generic manufacturer to accept a settlement without a reverse payment, the brand-name manufacturer will need to agree to an earlier entry date, thereby benefiting consumers. The settlement process will involve non-collusive arm's-length negotiations, in which the brand-name manufacturer seeks the latest entry date that it can achieve and the generic manufacturer seeks the earliest, and the date actually chosen will likely reflect the parties' perceptions of the strength of the infringement claim.

To be sure, there will likely be some cases in which a rule disfavoring reverse payments will cause paragraph IV suits to be litigated to judgment rather than settled on alternative terms. Even in those cases, however, the rule has countervailing advantages. The date of generic entry in such cases will reflect the *actual* exclusionary force of the patent, as determined through the judicial

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[4] During the past decade, the large majority of Hatch-Waxman settlements have involved such terms. See FTC, *Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, at 2 (FY 2012), http://www.ftc.gov/os/2013/01/130117mmareport.pdf.

processes fashioned by Congress based on adversary presentations by the brand-name and generic manufacturers, rather than an artificially deferred date reflecting supposed competitors' collusive agreement to split monopoly profits. See Pet. Br. 20-33.

Moreover, it is unexceptional that a legal rule might prevent parties from settling, if settling entails harm to third parties. In cases where reverse payments facilitate settlements that might otherwise be unobtainable, the payments achieve that result by inducing the generic manufacturer to accept a deferred date of entry, increasing (at consumers' expense) the total pool of profits for the brand-name and generic manufacturers combined, and thereby enhancing the likelihood that each party will find its own portion of the pool satisfactory. See Pet. Br. 8-9, 22-23. Because the potential for reverse payments to facilitate settlement is inextricably linked to their tendency to harm consumers, there is no sound reason to treat that potential as a ground for relaxed antitrust scrutiny.

5. Finally, respondents object that the "quick look" approach will be difficult to administer. First, respondents and their amici fear that parties and courts will have difficulty resolving disputes over whether the payment was compensation not for delay but instead for the parties' supposed side deal. Solvay Br. 47-48; Merck Amicus Br. 9-19. In defending against antitrust challenges, however, manufacturers should have ready access to whatever evidence supplied a business justification for their multi-million dollar transactions. And the antitrust court's ultimate inquiry should be no more difficult than in other fields of the law where a fact-finder is charged with reviewing a party's evaluation of a particular transaction or asset. See, *e.g.*, 11 U.S.C.

548(a)(1)(B)(i) (avoidance by bankruptcy trustee of certain transfers in which the debtor "received less than a reasonably equivalent value"); *Golden* v. *Cooper-Ellis*, 924 A.2d 19 (Vt. 2007) (valuation of assets in divorce); *Brehm* v. *Eisner*, 746 A.2d 244, 263 (Del. 2000) (corporate waste doctrine).

Second, respondents argue that, if this Court adopts the "quick look" approach, *private* antitrust suits challenging reverse-payment agreements will require a judicial inquiry into how the infringement suit would have been decided if it had been litigated to judgment. Solvay Br. 40; Actavis Br. 37-38. That is incorrect. To be sure, the plaintiff in such a suit can collect damages only by proving economic harm, which requires evidence as to the sequence of events that would likely have occurred if no reverse payment had been made. See Pet. Br. 55 n.11. The plaintiff might seek to discharge that burden, however, by instead showing that the brand-name and generic manufacturers would otherwise have settled the case with no reverse payment and an earlier entry date, rather than by attempting to prove that the case would have been litigated to judgment and the patentee would have lost.

In any event, respondents' argument conflates the question of whether the antitrust laws have been violated and the question of who may obtain what remedies for such a violation. See *Atlantic Richfield Co.* v. *USA Petroleum Co.*, 495 U.S. 328, 341-342 (1990) (distinguishing the two). Assumptions about the complexity of the damages phase of a private antitrust suit are no reason to abandon the prospective enforcement of core competition-law principles. That is particularly so because any remedial-phase difficulties would be largely transitional, since parties to paragraph IV suits can be

expected going forward to conform their settlements to whatever antitrust rule this Court adopts.

C. The "Quick Look" Approach Best Respects Congress's Intended Balance Between Innovation And Competition

Respondents and their amici argue that adopting the "quick look" approach would result in both "fewer [p]aragraph IV ANDA challenges and reduced incentives [for brand-name manufacturers] to innovate" than under the scope-of-the-patent approach. Actavis Br. 40; see Solvay Br. 35-38; PhRMA Amicus Br. 6-13; GPhA Amicus Br. 21. That argument has considerable internal tension, inasmuch as a reduced threat of paragraph IV litigation would seem to *increase* a patent's value. Moreover, the argument proves too much on the brand-name side because offering blanket immunity from the antitrust laws to all patent holders would likewise increase the incentives to innovate, yet there is no general "innovator exemption" from those laws. And on the generic side, even assuming that the hope of receiving a reverse payment might create an incentive to file a paragraph IV certification, that incentive will not ultimately further the purposes of the Hatch-Waxman Amendments if the generic manufacturer allows itself to be co-opted in return for a share of monopoly profits.

More fundamentally, none of those arguments answers the critical question here, which is whether Congress intended to offer brand-name drug manufacturers the particular incentive of monopoly profits secured by a reverse-payment agreement. The Patent Act and the Hatch-Waxman Amendments indicate that it did not.

1. "From their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to

invention itself and the very lifeblood of a competitive economy." *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989). Similarly, the Hatch-Waxman Amendments seek both to promote innovation and to speed generic drugs to market, and "the balance struck between these competing goals is quintessentially a matter for legislative judgment." *Teva Pharm. Indus. Ltd.* v. *Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005). As the government's opening brief explains (Br. 24-33, 43-44, 48), the "quick look" approach is consistent with the congressional balance struck in the Patent Act and the Hatch-Waxman Amendments, and the scope-of-the-patent approach is not. See also NACDS Amicus Br. 10-22; Law, Econ. & Bus. Professors Amicus Br. 8-9. In particular, neither of those laws legitimizes the use of reverse payments as a settlement term. And together they reflect a balance of benefits for generic manufacturers and protections from competition for brand-name manufacturers that would be upset by giving brand-name manufacturers the added opportunity to purchase still more protection by sharing their monopoly profits.

Solvay's reliance (Br. 35-36) on the risks of patent enforcement, as a justification for applying the scope-of-the-patent rule to reverse-payment agreements, is particularly misconceived. Those risks are a core part of the bargain in our system of judicially enforced patents, in which, *inter alia*, the presumption of validity is rebuttable (*Microsoft Corp.* v. *i4i Ltd. P'ship*, 131 S. Ct. 2238, 2245 (2011)), judgments adverse to patentees can have non-mutual collateral estoppel effect (*Blonder-Tongue Labs., Inc.* v. *University of Ill. Found.*, 402 U.S. 313, 350 (1971)), and infringement must be proved and is not simply presumed (*Railroad Co.* v. *Mellon*, 104 U.S. 112, 119 (1881)). Parties may settle to avoid those risks, but

they must take the bitter with the sweet; having contracted out of the risks of patent litigation, respondents are not entitled to the shield afforded to "[t]hose who petition the government for redress" through non-sham litigation, *Professional Real Estate Investors, Inc.* v. *Columbia Pictures Indus., Inc.*, 508 U.S. 49, 56 (1993). See Pet. Br. 26.

2. Relying on unenacted legislative proposals, Solvay asserts that "recent evidence of legislative intent suggests that Congress does *not* view 'reverse-payment' settlements as presumptively unlawful." Solvay Br. 56; see Actavis Br. 56-57. But this Court does not rely on unenacted bills to interpret federal law, see *Central Bank* v. *First Interstate Bank*, 511 U.S. 164, 186 (1994), especially when it is exercising its common law authority under the antitrust laws, where congressional intervention has been the exception. And what Congress *has* enacted is more telling: Its 2003 revisions to the Hatch-Waxman Amendments presuppose meaningful antitrust review of Hatch-Waxman settlement agreements by (1) requiring that such agreements be reported to the FTC and Department of Justice, and (2) providing for the forfeiture of any generic exclusivity period if such an agreement is challenged by the government and held to "violate[] the antitrust laws." Medicare Prescription Drug, Modernization, and Improvement Act, Pub. L. No. 108-173, §§ 1102(a)(2), 1111-1118, 117 Stat. 2458, 2461-2464 (codified at 21 U.S.C. 355(j)(5)(D)(i)(V) and note).

D. Adopting The Scope-Of-The-Patent Approach Would Immunize And Encourage Collusive Behavior

Pharmaceutical manufacturers can be expected to conform their primary conduct to whatever rule the Court adopts in this case. And, as the government's

opening brief explains, antitrust law seeks to achieve its goals by channeling companies' pursuit of their own self-interest into conduct that is likely to benefit consumers. See Pet. Br. 28, 39; *Premier Elec. Constr. Co.* v. *National Elec. Contractors Ass'n*, 814 F.2d 358, 369-370 (7th Cir. 1987) (Easterbrook, J.).

Adopting the "quick look" approach will discourage use of a particular settlement term (a reverse payment) that appears to be essentially unknown outside the Hatch-Waxman context. Parties will remain free, however, to settle paragraph IV litigation on other terms, or to litigate their disputes to judgment in the (likely rare) cases in which the parties are willing to settle if, but only if, a reverse payment can be used. Although the prospect of some additional litigation is appropriately viewed as a cost of the "quick look" approach, the approach has countervailing advantages even in that category of cases, since the ultimate date of generic entry will reflect the *actual* exclusionary force of the patent. See pp. 12-13, *supra*.

By contrast, this Court's adoption of the scope-of-the-patent approach would encourage collusive behavior that harms consumers. As even respondents' preferred economists acknowledge, "a safe harbor for agreements that settle patent disputes would foster anticompetitive outcomes that benefit the parties to the patent disputes but that harm consumers." John P. Bigelow & Robert D. Willig, *"Reverse Payments" in Settlements of Patent Litigation:* Schering-Plough, K-Dur, *and the FTC (2005)*, in *The Antitrust Revolution* 248, 274 (John E. Kwoka, Jr. & Lawrence J. White eds., 5th ed. 2009). Given the pharmaceutical industry's economics, the scope-of-the-patent approach would create a powerful incentive for generic manufacturers in paragraph IV

litigation to agree to deferred dates of entry (*i.e.*, dates significantly later than the strength of their negotiating positions would otherwise enable them to obtain), since both the brand-name and generic manufacturers' profits can be increased if the brand-name's monopoly can be extended and the monopoly profits can be shared. See Pet. Br. 22-23.

That sort of collusive behavior is antithetical to the federal competition laws, and it would systematically disserve consumer interests. Treating such agreements as legitimate would be especially untoward in light of Congress's effort, through the 180-day exclusivity period available to a successful first filer of a paragraph IV certification, to increase the incentives for generic competition. See Pet. Br. 31; 21 U.S.C. 355(j)(5)(B)(iv). A generic first filer who accepts a reverse payment to defer market entry does not simply fail to compete vigorously; its overall course of conduct impedes the competitive potential of other generic manufacturers as well, since second and later filers are not entitled to the exclusivity period and therefore have diminished incentives to bear the costs and regulatory burdens of seeking market entry before the patent expires. See Apotex Amicus Br. 11-20.

E. This Court's Patent-Licensing Precedents Do Not Justify Respondents' Scope-Of-The-Patent Approach

Respondents' affirmative support for their scope-of-the-patent approach principally consists of decisions of this Court addressing the antitrust limits on the exercise of patent rights. Solvay Br. 14-19; Actavis Br. 47-51; Par/Paddock Br. 31-46. Respondents' reliance on those precedents is misplaced.

1. Respondents contend that under this Court's decisions, setting aside frauds and shams, "antitrust scruti-

ny" is appropriate "[o]nly if a restraint falls outside the scope of a patent." Solvay Br. 9. The scope-of-the-patent approach plays a useful role in antitrust analysis by identifying agreements that are per se unlawful (*viz.*, agreements not to compete unconnected with any colorable patent right). It does not logically follow, however, that a patentee enjoys an exemption from antitrust scrutiny for every possible action—whether unilateral or by agreement—that would achieve the same exclusionary effect as a court injunction.

By "scope of the patent," moreover, respondents do not refer to the *actual* exclusionary effect of the patent, as determined through judicial proceedings resolving contested issues of validity and infringement. Rather, they refer to the "exclusionary effect * * * the patent *potentially* provides," Solvay Br. 15 (emphasis added), *i.e.*, the exclusionary force that the patentee *alleges* it to have (so long as the patent was not procured through fraud and the allegations of infringement are not a sham). Use of that baseline would be particularly unsound when addressing the antitrust implications of an agreement between potential competitors who have asserted inconsistent positions on the pertinent issues of patent validity and/or infringement. See Pet. Br. 43-44; pp. 3-4, *supra*.

2. None of the decisions respondents cite from this Court compels the rule they advocate, and adoption of the government's "quick look" approach to reverse-payment agreements would not call any of those decisions into question. Most of the decisions addressed challenges to particular terms of agreements under which a patent was licensed (or a patented product was

sold).[5] A licensor and its licensee stand in a vertical relationship as to the license agreement's terms, and licensing arrangements are generally procompetitive because they tend to present opportunities for increased output. The scope-of-the-patent approach, by contrast, would apply to a horizontal agreement between a brand-name manufacturer and its would-be generic competitor; that approach would immunize agreements regardless of whether they involve a license, and indeed would permit agreements not to compete until patent expiration. Such agreements by definition cannot result in increased output. See 12 Herbert Hovenkamp, *Antitrust Law* ¶ 2046c, at 337-338 (3d ed. 2012) (distinguishing on this ground between licensing agreements and reverse-payment settlements).

The procompetitive effect of a license may be most evident when it is undisputed that the licensed conduct would otherwise infringe a valid patent. But even when a license is used to resolve an actual or potential dispute about patent validity or infringement, the license may be procompetitive, particularly if its terms reflect a negotiating dynamic in which consumers' interests are adequately protected. By contrast, a reverse payment severs the alignment of interests that would otherwise exist between the generic manufacturer and consumers when the parties to paragraph IV litigation negotiate a set-

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[5] See, *e.g.*, *United States* v. *Line Material Co.*, 333 U.S. 287 (1948) (addressing validity under antitrust laws of terms of sublicenses of multiple cross-licensed patents); *United States* v. *United States Gypsum Co.*, 333 U.S. 364 (1948) (addressing validity under antitrust laws of terms on which patent was licensed); *United States* v. *General Elec. Co.*, 272 U.S. 476 (1926) (same); *General Talking Pictures Corp.* v. *Western Elec. Co.*, 304 U.S. 175 (1938) (patent-infringement suit addressing sale by patent licensee of patented article in violation of license).

tlement, and realigns the generic manufacturer's interests with the brand-name manufacturer's desire to preserve its monopoly.

In a somewhat different category is *Dawson Chemical Co.* v. *Rohm & Haas Co.*, 448 U.S. 176 (1980), in which the patentee had refused to license to sellers of an unpatented chemical its patent on a method of using that chemical, a practice the sellers claimed in their defense was patent misuse. As Solvay points out (Br. 18), this Court assumed the validity of the patent for purposes of the misuse defense. The Court adopted that assumption, however, simply because the courts below had not yet passed on the sellers' challenges to the validity of the patent. *Dawson Chem.*, 448 U.S. at 185 n.5. The Court's decision clearly assumed that the sellers, who had been sued for patent infringement, would ultimately be heard on their invalidity challenge. This case, by contrast, involves generic manufacturers' receipt of cash payments in exchange for their promise *not* to contest patent validity or infringement.

Finally, Solvay's reliance (Br. 16-18) on *Standard Oil Co.* v. *United States*, 283 U.S. 162 (1931), is particularly misplaced. That case likewise involved licensing agreements rather than an agreement not to compete. And Solvay is wrong in contending that the permissible cross-licensing of patents in the challenged settlement agreement, like a reverse payment, "g[ave] accused infringers something 'they could not hope to obtain even if they prevailed in litigation.'" Br. 34 (quoting Pet. Br. 30). Those cross-licenses mirrored a judicial decree of infringement with a remedy of a compulsory license with prospective running royalties rather than an injunction (an established form of remedy in patent cases, see, *e.g.*, *Innogenetics, N.V.* v. *Abbott Labs.*, 512 F.3d 1363, 1379-

1381 (Fed. Cir. 2008)). In any event, if the scope-of-the-patent approach were correct, this Court in *Standard Oil* should not have bothered to analyze the arrangements under the rule of reason (see 283 U.S. at 170-179), but instead should have simply disposed of the case on the ground that the government had failed to prove at trial (and did not contend on appeal) that the patent litigation was pretextual or the settlements were entered in bad faith, see *id.* at 180.

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For the foregoing reasons and those stated in our opening brief, the judgment of the court of appeals should be reversed and the case remanded for further proceedings.

Respectfully submitted.

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Solicitor General

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AMICUS CURIAE BRIEF

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FEDERAL TRADE COMMISSION,
PETITIONER,
v.
WATSON PHARMACEUTICALS, INC. ET AL,
RESPONDENTS.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

BRIEF FOR AARP, AMERICAN MEDICAL ASSOCIATION, NATIONAL LEGISLATIVE ASSOCIATION FOR PRESCRIPTION DRUG PRICES AND U.S. PUBLIC INTEREST RESEARCH GROUPS AS AMICI CURIAE IN SUPPORT OF PETITIONER

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Jonathan D. Rockoff, *More Balk at Cost of Prescriptions*, Wall St. J., Oct. 12, 2010 (citing data from a Wolters Kluwer Pharma Solutions study) , *available at* http://online.wsj.com/article/SB10001424052748703927504575540510224649150.html 13

STATEMENTS OF INTEREST OF AMICI CURIAE[1]

Amicus Curiae AARP is a nonpartisan, nonprofit organization dedicated to addressing the needs and interests of people aged fifty and older. AARP has a long history of advocating for access to affordable health care and for controlling costs without compromising quality. Affordable prescription medication is particularly important to the older population which, because of its higher rates of chronic and serious health conditions, has experienced an increasing rate of prescription drug use. From 2005 to 2008, sixty-five percent of persons age sixty-five and older used three or more prescriptions within the past month, versus just thirty-five percent who did so from 1988 to 1994. Centers for Disease Control and Prevention, *Health, United States, 2011*, Table 99 (May 2012), *available at* http://www.cdc.gov/nchs/data/hus/hus11.pdf#list tables.

Significantly, in a 2005 AARP survey, one in four Americans, ages 50 and older, who took a

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[1] In accordance with Supreme Court Rule 37.6, Amici Curiae state that: (1) no counsel to a party authored this brief, in whole or in part; and (2) no person or entity, other than amici, their members and counsel have made a monetary contribution to the preparation or submission of this brief. Parties were timely informed with 10-days notice of the intent to file this amicus brief, and the written consents of the parties to the filing of this brief have been filed with the Clerk of the Court pursuant to Supreme Court Rule 37.2.

prescription drug in the past five years said they did not fill a prescription written by their doctor in the past two years. Cost was reported as the main deterrent. Linda L. Barrett, AARP, *Prescription Drug Use Among Midlife and Older Americans* 2 (2005), *available at* http://assets.aarp.org/rgcenter/health/rx_midlife_plus.pdf. Since prescription drug spending has skyrocketed over the last decade and a half, and national health expenditures on prescription drugs have quadrupled, AARP supports the Medicare Part D prescription drug benefit, and continues to advocate for lower prescription drug costs for all consumers. *See, e.g.*, AARP, *Rx PriceWatch Report: Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Medicare Beneficiaries 2005 to 2009* (March 2012), *available at* http://www.aarp.org/content/dam/aarp/research/public_policy_institute/health/rx-pricewatch-march-2012-AARP-ppi-health.pdf.

Amicus Curiae American Medical Association ("AMA") is the largest professional association of physicians, residents and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all United States physicians, residents and medical students are represented in the AMA's policy making process. The objectives of the AMA are to promote the science and art of medicine and the betterment of public health. The AMA joins this brief because of its concern that pay-for-delay agreements extend patent monopolies excessively. These agreements artificially inflate health care costs and obstruct physicians'

ability to treat their patients with necessary medications. The AMA believes that pay-for-delay agreements undermine the Hatch-Waxman Act's compromise between the interest in spurring innovation through the patent system and the interest in fostering competition through the development of generic drugs.

Amicus Curiae National Legislative Association for Prescription Drug Prices ("NLARx") is a national nonprofit, nonpartisan organization of state legislators who support policies to reduce prescription drug prices and expand access to affordable medicines; and has promoted policies since 2000 to expand access to generics drugs and increase competition in the market place.

Amicus Curiae U.S. PIRG, the federation of state Public Interest Research Groups ("PIRGs"), works on behalf of American consumers, through public outreach to advocate for affordable health care and prescription drugs. U.S. PIRG's mission is to deliver result-oriented public interest activism that protects consumers, encourages a fair, sustainable economy, and fosters responsive, democratic government. U.S. PIRG regularly advocates before state and federal regulators and legislators on both consumer protection and competition policy issues in the payment system marketplace.

SUMMARY OF ARGUMENT

The ruling below that exclusion payment agreements are with few exceptions *per se* lawful under Section 1 of the Sherman Act will have a devastating impact on American consumers if left to stand. Prescription drug spending in the United States has skyrocketed over the last two decades. Competition from generic drugs is the most effective means of slowing the spiraling cost of pharmaceuticals.

Generics typically sell for a fraction of the cost of their branded counterparts. When generics enter the market they quickly capture the majority of unit sales. Overall generics have saved consumers $1.07 trillion between 2002 and 2011. Press Release, Generic Pharmaceutical Association, New Study Finds Use of Generic Prescription Drugs Saved Consumers and the U.S. Health Care System $1 Trillion over Past Decade (Aug. 2, 2012), *available* at http://www.gphaonline.com/media/press-releases/2012/new-study-finds-use-generic-prescription-drugs-sav ed-consumers-and-us-heal.

Recognizing the clear consumer benefit that accompanies generic drug competition, Congress sought to speed up generic entry by enacting the Hatch-Waxman Act (Public Law 98-417).

Brand-name firms have used exclusion agreements to delay entry of generics by an average of seventeen months and to terminate patent challenges that would otherwise generate *billions* of

dollars in consumer savings. Delaying the entry of affordable generic drugs not only prevents competition, but the lack of low cost treatment options reverberates throughout the entire health care system. Even for those patients who are insured but who are on fixed or limited incomes, having a generic option is often the difference between having access to a health care treatment and not having any treatment option at all. Economists at the FTC estimate that, if nothing changes, exclusion payment settlements will cost consumers $35 billion over the next ten years. Fed. Trade Comm'n, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 2 (Jan. 2010), *available at* http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf. If *Watson* remains controlling law, the patent-challenge provisions of the Hatch-Waxman Act would be eviscerated, and American consumers would be left to pay the price.

REASONS FOR REVERSING THE ELEVENTH CIRCUIT

INTRODUCTION

The ruling below that exclusion payment agreements are with few exceptions *per se* lawful under Section 1 of the Sherman Act will have a devastating impact on American consumers if left to stand. According to the Eleventh Circuit, the presumption of validity enjoyed by patents, 35 U.S.C. § 282, entitles patentees to pay alleged infringers not to contest validity and to stay out of the market so long as the settlement falls within the exclusionary

scope of the patent. *FTC v. Watson Pharm.*, 677 F.3d 1298, 1309, 1312 (2012).

Competition from generic drugs is one of the most effective means of slowing the spiraling cost of pharmaceuticals. Generics typically sell for one-third to one-fourth the cost of their branded counterparts and quickly capture the majority of unit sales, saving consumers literally hundreds of millions of dollars on a blockbuster drug such as Solvay's AndroGel™. If generic entry had occurred it would have significantly reduced the cost of the product and generics would have captured a significant share of the market. See AndroGel™ Sales Data (Nov. 2012), http://www.drugs.com/stats/AndroGel.

I. THE ELEVENTH CIRCUIT'S DECISION THAT EXCLUSION PAYMENTS ARE *PER SE* LAWFUL DEFEATS THE PROTECTIONS OF THE HATCH-WAXMAN ACT AND UNDERMINES ENFORCEMENT OF THE SHERMAN ACT

Prescription drug spending in the United States has skyrocketed over the last two decades from $40 billion in 1990 to over $320 billion in 2011. Kaiser Family Foundation, *Prescription Drug Trends* 1 (Sept. 2008), *available at* http://www.kff.org/rxdrugs/upload/3057_07.pdf; Press Release, IMS Health, Breakthrough Treatments, Fewer Doctor Office Visits, Reduced Use of Medicines Impact U.S. Healthcare in 2011, According to IMS Study (Apr. 4, 2012), *available at* http://www.imshealth.com/portal/site/ims/menuitem.d248e29c86589c9c30e81c0

33208c22a/?vgnextoid=81c63fc68b876310VgnVCM10000076192ca2RCRD.

The rate of increase in many brand-name prescription drug prices continues to accelerate and outpace inflation. For example, in the twelve-month period ending in March 2010, the price of brand name prescriptions most widely used by Medicare beneficiaries increased by 9.7 percent, the highest rate of increase observed since AARP began tracking these prices in 2002. AARP, *Rx Watchdog Report: Brand Name Drug Prices Continue to Climb Despite Low General Inflation Rate* 1 (May 2010), *available at* http://assets.aarp.org/www.aarp.org_/articles/health/207961rxwatchdog0510.pdf.

When clinically appropriate for a patient, using a generic drug over a branded project can be the most effective way to slow the spiraling cost of pharmaceuticals. Generics typically sell for a fraction of the cost of their branded counterparts and quickly capture the majority of unit sales, thus having saved consumers over $1.07 trillion between 2002 and 2011. Press Release, Generic Pharmaceutical Association, New Study Finds Use of Generic Prescription Drugs Saved Consumers and the U.S. Health Care System $1 Trillion over Past Decade (Aug. 2, 2012), *available* at http://www.gphaonline.com/media/press-releases/2012/new-study-finds-use-generic-prescription-drugs-saved-consumers-and-us-heal. A recent survey found that the prices of the most commonly used brand-name medications increased by 13.3%, while prices for generic medications fell 21.9% for the 12 months ending

September 2012. Press Release, Express Scripts, Express Scripts Publishes Inaugural Drug Trend Quarterly (November 28, 2012), *available at* http://phx.corporate-ir.net/phoenix.zhtml?c=69641&p=irol-newsArticle&ID=1762296&highlight. The gap in growth rates in the cost between branded drugs and generics is the largest recorded since Express Scripts began collecting this data in 2008.

When patients and their prescribers who may have a lower-cost generic option available select instead higher-cost branded drugs, this "generates unnecessary medical expenditures, the costs of which are borne by the public in the form of higher copayments, increased health insurance costs, and higher Medicare and Medicaid expenses," according to research published in January 2013. Eric G. Campbell et al., *Physician Acquiescence to Patient Demands for Brand-Name Drugs: Results of a National Survey of Physicians*, JAMA Internal Medicine, January 7, 2013, *available at* http://archinte.jamanetwork.com/article.aspx?articleid=1555818.

Recognizing the clear consumer benefit that accompanies generic drug competition, Congress sought to speed up generic entry by enacting the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355, commonly referred to as the Hatch-Waxman Act, which "institutionalize[d] and provide[d] incentive for a system of attacks on presumptively valid patents" by generic manufacturers. *Innovation and Patent Law Reform: Hearings on H.R. 3285, H.R. 3286, and H.R.*

3605 Before the Subcomm. on Courts, Civil Liberties, and the Administration of Justice of the H. Comm. on the Judiciary, 38th Cong. 2d Sess., Part 1, at p. 444 (1984).

In creating the incentive to challenge patents, Congress was not seeking to enrich the generic drug manufacturers. Hatch-Waxman challenges were supposed to be vehicles for earlier entry of generic drugs into the marketplace, thus giving consumers earlier access to lower-priced prescription drug alternatives. H. R. Rep. No. 98-857, pt. 1 at 1 (1984), *reprinted* in 1984 U.S.C.C.A.N. 2647 (explaining that the purpose of the Hatch-Waxman Act "is to make available more low cost generic drugs by establishing a generic drug approval procedure"). Indeed, generics make up nearly seventy percent of drugs prescribed today, whereas generics constituted only twelve percent of prescription drugs dispensed prior to the passage of the Hatch-Waxman Act. *See* AARP, *Rx Watchdog Report*, Vol.6, Issue 4 at 4 (May 2009), *available at* http://www.aarp.org/content/dam/aarp/aarp_foundation/litigation/amicus_brief_pdfs/Louisiana_Wholesale_Drug_Co_v_Bayer.pdf. *See also*, Food and Drug Administration, *Protecting America's Health Through Human Drugs: Greater Access to Generic Drugs* (Jan. 2006), *available at* http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143545.htm.

The rise of exclusion payment agreements, however, has had a drastic effect on generic drug entry prior to patent expiration. Brand-name firms have used exclusion agreements to delay entry of

generics by an average of seventeen months and to terminate patent challenges that would otherwise generate *billions* of dollars in consumer savings. Fed. Trade Comm'n, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 2 (Jan. 2010), available at http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf. See also data from the AARP Public Policy Institute examining brand-name drug price increases for drugs closest to patent expiration. AARP, *Rx Price Watch Report: Retail Prices for Widely Used Brand Name Drug Increase Considerably Prior to Generic Competition* 4-6 (March 2011), *available at* http://www.aarp.org/health/drugs-supplements/info-08-2010/rx_price_watch.html.

Under the exclusion payment agreement here, for example, Solvay paid the generic competitors Watson, Par and Paddock between $31-42 million annually in exchange for the generics' agreement to stay out of the market for 9 of the remaining 15 year life of the AndroGel™ patent. In other words, Defendants' agreement ensured that consumers would have to wait another 9 years to buy lower-priced generic AndroGel™. This delayed generic entry is the antithesis of what Congress intended when it enacted the Hatch-Waxman Act. See *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991) ("Congress sought to get generic drugs into the hands of patients at reasonable prices-fast.").

II. INCREASED USE OF EXCLUSION PAYMENTS PREVENTS COMPETITION AND HARMS CONSUMERS

At the end of 2008, brand name drug manufacturers were attempting to block generic entry on products with roughly $90 billion in pharmaceutical sales. Fed. Trade Comm'n, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 2 (Jan. 2010), available at http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf [hereinafter FTC, Pay-for-Delay]. Delaying the entry of affordable generic drugs not only prevents competition, but the lack of low cost treatment options reverberates throughout the entire health care system. The price of a brand drug can be prohibitive for uninsured patients who do not have help covering the cost of their prescription drugs. Even for those patients who are insured but who are on fixed or limited incomes (but who may not qualify for Medicare Part D's low-income subsidy), having a generic option is often the difference between having access to a health care treatment and not having any treatment option at all.

The enormous consumer gains resulting from generic entry are well documented. The Federal Trade Commission (FTC) has cited that successful patent challenges to just four major brand-name drugs (Prozac, Zantac, Taxol and Platinol) have saved consumers more than $9 billion. Prepared Statement of the Federal Trade Commission before the Committee on the Judiciary of the United States Senate, *Anticompetitive Patent Settlements in the*

Pharmaceutical Industry: The Benefits of a Legislative Solution at 4 (Jan. 17, 2007), *available at* http://www.ftc.gov/speeches/leibowitz/070117Anticompetitivepatentsettlements_senate.pdf. Had exclusion payments been permissible, none of these consumer savings likely would have occurred.

In the midst of Barr Laboratories' challenge to the patents protecting Eli Lilly's drug Prozac, for example, Barr stated that it would settle only if the settlement included an exclusion payment of at least $200 million. *See* Bethany Mclean, *A Bitter Pill*, Fortune, Aug. 13, 2001, at 5. Lilly refused the demand because, as acknowledged by Lilly's CEO, "such a settlement violated antitrust laws, and it isn't morally right." *Id.* So Barr continued litigating the case and ultimately obtained a judgment invalidating the Prozac patents. The resulting early entry of generic Prozac saved consumers an estimated $2.5 billion. *See* Comment of the Generic Pharm. Ass'n in Support of Citizen Pet. Docket No. 2004P-0075/CP1 3 (May 21, 2004), *available at* http://www.fda.gov/ohrms/dockets/dailys/04/June04/060404/04p-0075-c00003-vol1.pdf.

Allowing exclusion payments that "grant monopoly privileges to the holders of invalid patents," *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 100-01 (1993), results in lost consumer health and welfare greatly disproportionate to the relatively modest costs of patent litigation. *See* Herbert Hovenkamp et al., *Balancing Ease & Accuracy In Assessing Pharmaceutical Exclusion Payments*, 88 Minn. L. Rev. 712, 717 (Feb. 2004).

Those increased costs may ultimately harm the well-being of patients and the delivery of healthcare. Patients may skip doses of prescribed medicines due to their high cost. Barrett, *supra*. For the same reason, they may also simply decline to have a prescription filled. This phenomenon, sometimes known as "abandonment," has been on the rise since 2010. Patients with private health insurance abandoned nearly one in ten new prescriptions for brand-name drugs in the second quarter of 2010. This increase comes as patients see a rise in the cost of prescription medications. Kaiser Family Foundation, *Prescription Drug Costs: Background Brief* (Dec. 2012), *available at* http://www.kaiseredu.org/Issue-Modules/Prescription-Drug-Costs/Background-Brief.aspx. As an example, a mother in Montana who arrived at a pharmacy to discover that medication for her depression and her son's asthma would cost her $335 despite her private insurance. The mother abandoned both prescriptions before purchasing a cheaper, alternative medication for her son. Jonathan D. Rockoff, *More Balk at Cost of Prescriptions*, Wall St. J., Oct. 12, 2010 (citing data from a Wolters Kluwer Pharma Solutions study), *available at* http://online.wsj.com/article/SB10001424052748703927504575540510224649150.html.

A Consumer Reports survey found that 18% of people with prescription drug coverage declined to fill prescriptions in 2012 because of cost, up from 16% in 2011, and 45% of people without prescription drug coverage skipped a refill due to costs, up from 27% in

2011. Consumer Reports, *Sluggish Economy Forces Americans to Cut Corners to Pay for Medications: Those without Prescription Drug Coverage Nearing Crisis Point* (Sept. 2012), *available at* http://www.consumerreports.org/cro/2012/09/sluggish-economy-forces-americans-to-cut-corners-to-pay-for-medications/index.htm.

When patients do not obtain necessary treatment because no financially feasible options are available, conditions left untreated can worsen and may result in a higher cost of care over time. Statement for the Record, American Medical Association before the Subcomm. on Commerce, Trade, and Consumer Protection for the House Committee on Energy and Commerce, *Impact of "Pay-for-Delay" Settlements On Patient Access to Affordable Generics and Overall Health Care System Costs* (April 13, 2009). Economists at the FTC estimate that, if nothing changes, exclusion payment settlements will cost consumers $35 billion over the next ten years. FTC, Pay-for-Delay, *supra*, at 2; *see also* C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 650 (2009) (estimating that exclusion payments have already cost consumers over $12 billion).

For this reason, one of the FTC's top priorities has been stopping "pay-for-delay" agreements between brand-name pharmaceutical companies and generic competitors that delay the entry of lower-priced generic drugs into the market. FTC Chairman Leibowitz noted that, "[a]greements to eliminate

potential competition and share the resulting profits are at the core of what the antitrust laws proscribe, and for that reason the Commission believes strongly that these pay-for-delay settlements are prohibited under the antitrust laws." Prepared Statement of The Fed. Trade Comm'n before the U.S. Senate Comm. On the Judiciary, Subcommittee on Antitrust, Competition Policy and Consumer Rights, *How the Federal Trade Commission Works to Promote Competition and Benefit Consumers in a Dynamic Economy*, (June 9, 2010) *available at* http://www.ftc.gov/os/testimony/100609dynamiceconomy.pdf.

Unfortunately, these pay for delay agreements are increasing. An FTC report to Congress released this month found that the number of pay for delay agreements increased by over 40% in the year ending September 2012 excluding generic competition for drugs accounting for over $8.3 billion in sales annually. Bureau of Comp., Fed. Trade Comm'n, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in Fiscal Year 2012* 1 (Jan. 2013), *available at* http://www.ftc.gov/os/2013/01/130117mmareport.pdf.

If Watson remains controlling law and allows exclusion payments between brand-name and generic firms through patent litigation settlements, these settlements will increase and consumers will continue to pay more for vital drugs and the patent-

challenge provisions of the Hatch-Waxman Act will be eviscerated.

III. THE ELEVENTH CIRCUIT'S DECISION THAT EXCLUSION PAYMENTS ARE *PER SE* LAWFUL WILL NOT PROTECT INCENTIVES TO INNOVATE

Congress passed the Hatch-Waxman Act with the explicit purpose "to speed the introduction of low-cost generic drugs to market," *Caraco Pharm. Labs. Ltd.* v. Novo Nordisk A/S, 132 S. Ct. 1670, 1676 (2012). The Hatch-Waxman Act employs two mechanisms to facilitate generics' entry to market. First, it provides an avenue for an accelerated regulatory review by providing for a generic to demonstrate its bioequivalency to another drug that has successful navigated the onerous New Drug Application ("NDA") process. 21 U.S.C. § 355(j)(2)(A)(ii) and (iv) (2006). Second, the Hatch-Waxman Act provides the generic with a mechanism for quickly resolving a patent infringement lawsuit by a brand manufacturer. 21 U.S.C. § 355(j)(2)(A)(vii)-(viii) (2006). These mechanisms invite generic competition and innovation with the stated goal of leading to low-cost generic products becoming available for consumers.

Some may argue that the Eleventh Circuit's rule of *per se* legality is necessary to provide the incentive for generic firms to innovate and attempt to enter the market. But this argument presupposes that generic firms will not challenge a patent unless it is able to settle the litigation *with an exclusion*

payment. Such an argument is inconsistent with the facts, public policy, and law.

First, earlier in the last decade, when the law condemned exclusion payments, branded and generic firms entered into numerous settlements without exclusion payments. Exclusion payments are a relatively recent development, and there was significant generic entry and innovation before these payments occurred. Moreover, parties frequently settle patent infringement litigation without extending the terms of the settlement to include exclusionary terms. *See, e.g.*, Herbert Hovenkamp et al., *Balancing Ease & Accuracy In Assessing Pharmaceutical Exclusion Payments*, 88 Minn. L. Rev. 712, 712-14 (Feb. 2004). In fact, in 2012 more than 70% of ANDA settlements did not include an agreement by the generic firm to delay entry into the market in exchange for compensation from the brand firm. Bureau of Comp., Fed. Trade Comm'n, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in Fiscal Year 2012* 2 (Jan. 2013), available at http://www.ftc.gov/os/2013/01/130117 mmareport.pdf. This suggests that concerns that reverse payments are needed for product innovation are overblown, and instead that reasonable, pro-consumer settlements that do not include exclusion agreements are still attainable.

Second, the drafters of the Hatch-Waxman Act intended that generics would foster competition through patent challenges, and specifically provided

other mechanisms to promote innovation. *See* Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 Mich. L. Rev. 37, 43-45 (Oct. 2009) (discussing patent term extensions, non-patent-based exclusivity, and the automatic 30-month stay of FDA approval).

Third, a rule of *per se* legality distorts the incentive system. Rather than a system that provides incentives and rewards for inventing non-infringing products or successfully invalidating patents, a rule of *per se* legality encourages a generic firm to sue to settle and secure the exclusion payment. The Third Circuit recognized this paradigm and reasoned that it is "logical to conclude that the *quid pro quo* for [a reverse] payment was an agreement by the generic firm to defer entry beyond the date that represents an otherwise reasonable litigation compromise." *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (2012) (cert pending). If these payments are effectively scrutinized under the antitrust laws, the incentives would be restored to what Congress intended – a spur to generic entry.

It is important not to confuse the idea of incentivizing generic innovation with incentivizing generic challenges to brand patents. The two are not the same. Generic investment in challenging the validity or infringement of brand patents will benefit consumers only if it leads to additional entry. If, however, a generic's Abbreviated New Drug Application ("ANDA") application is little more than a litigation tactic to secure a settlement, then the practice in question does not promote innovation and

is not beneficial for society. Instead, it is a mere transfer of supracompetitive profits from the brand to the generic at the expense of the consumer welfare contemplated by the Hatch-Waxman Act.

CONCLUSION

The judgment of the Court of Appeals should be reversed.

January 29, 2013

Respectfully submitted,

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AMICUS CURIAE BRIEF

No. 12-416

RECORD AND BRIEF

IN THE

Supreme Court of the United States

FEDERAL TRADE COMMISSION,

Petitioner,

v.

ACTAVIS, INC., *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICUS CURIAE*

The American Intellectual Property Law Association ("AIPLA") is a national bar association with approximately 15,000 members. AIPLA's members are engaged in all aspects of patent, trademark, copyright, and unfair competition law, as well as other fields of law affecting intellectual property rights. They include lawyers who practice in law firms and corporate law departments, serve in government agencies and public interest organizations, and teach in law schools and universities. Representing both the owners and the users of intellectual property, AIPLA speaks for the full spectrum of interests relating to intellectual property law.[1]

Since its formation in 1897, AIPLA has worked to maintain high standards of professionalism and ethics among intellectual property lawyers, to improve the laws relating to intellectual property and their interpretation by the courts, and to provide legal education to its members and the public on intellectual property issues. AIPLA takes an active role in shaping American intellectual property policy through its work on legislation, federal regulations, and intellectual property cases in the courts.

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1. In accordance with Supreme Court Rule 37.6, *amicus curiae* states that this brief was not authored, in whole or in part, by counsel for a party, and no monetary contribution to the preparation or submission of this brief was made by any person or entity other than the *amicus curiae* or its counsel. After reasonable investigation, AIPLA believes that no member of its Board or *Amicus* Committee who voted to file this brief, or any attorney in the law firm or corporation of such a member, represents a party to this litigation. In accordance with Supreme Court Rule 37.3(a), all parties have consented to the filing of this brief in letters on file with the Clerk of the Court.

AIPLA submits this brief to assist the Court in understanding why the "scope of the patent" rule applied by the Eleventh Circuit is critical to preserving the important patent rights created by Congress, which are designed to advance consumer welfare by encouraging invention and risk-taking. The presumption of an antitrust violation urged by the Federal Trade Commission ("FTC") is inconsistent with patent law because it would significantly interfere with the economic rights intended by Congress for the resolution of patent litigation and will thus only harm consumers in the long run.

BACKGROUND

This case brings into focus the boundary between patent law and antitrust law for patent settlement agreements. Although the particular settlements at issue were entered into between branded and generic drug makers to resolve drug patent litigation arising in the context of the Drug Price Competition and Patent Restoration Act of 1984 (the "Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585, the resolution of this case will likely have broad implications for all manner of patent settlements, and potentially for many common patent licensing arrangements between potential competitors.

1. Like many settlements of Hatch-Waxman litigation (and other patent settlements and licensing arrangements), the agreements negotiated among respondents expressly permitted the generic maker (the would-be competitor) to begin marketing the generic version of the branded drug on an agreed date before the expiration of the drug patent. The agreements also included the payment of money from the branded company (the patent holder)

to the generic maker (what the FTC calls a "reverse payment"). For many years, the FTC has pursued an enforcement policy condemning such patent settlements as unreasonable restraints of trade in violation of section 1 of the Sherman Act, 15 U.S.C. § 1, and as unfair methods of competition under section 5 of the FTC Act, 15 U.S.C. § 45. The FTC presumes that "reverse payment" patent settlements are unlawful under the antitrust laws (with no analysis required), unless the settling parties can prove that the payment does not exceed a reasonable estimate of litigation costs or is required to achieve some other offsetting competitive benefits; absent such a showing, the FTC says, "it is logical to conclude that the *quid pro quo* for [the] payment is an agreement by the [would-be competitor] to defer entry beyond the date that represents an otherwise reasonable litigation compromise." Pet. Br. at 34-35 (internal quotation marks omitted); *see id.* at 29, 33-36; *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012) (quoting and adopting the FTC analysis), *cert. pending*, Nos. 12-245 & 12-265 (U.S. filed Aug. 24 & 29, 2012). The FTC maintains that such a "pay for delay" *quid pro quo* in a patent settlement should be declared a *per se* violation of the Sherman Act.

2. Three courts of appeals, including the Eleventh Circuit here, have rejected the FTC's position and have, instead, applied the so-called "scope of the patent" rule to reverse-payment patent settlements. Courts have long relied on a similar "scope of the patent" principle in addressing antitrust challenges to restrictions on competition commonly included in patent licensing arrangements (such as pricing requirements, territorial restrictions, restrictions on production output or sales, time limitations, and other restraints). *See, e.g.*, *United*

States v. General Electric Co., 272 U.S. 476 (1926) (pricing restrictions); *United States v. Studiengeselschaft Kohle*, 670 F.2d 1122 (D.C. Cir. 1981) (restrictions on sales). Under this principle, courts hold that a patentee has the right under patent law to insist on such restraints—and the restraints are therefore permitted under the antitrust laws—as long they do not exceed the exclusionary scope of the patent. *See General Electric*, 272 U.S. at 488; *Studiengeselschaft*, 670 F.2d at 1128 (licensing restriction on sales held lawful because the patent holder "sought nothing beyond what the patent itself gave it").

3. The courts of appeals that have applied a similar rule to reverse-payment patent settlements in the Hatch-Waxman context, like the Eleventh Circuit, have held that such settlements do not violate the antitrust laws provided they do not purport to expand the presumptive exclusionary scope of the drug patent beyond its term of years or beyond the claims covered by the patent, unless those challenging the settlement establish that the patent was procured by fraud or that the underlying patent infringement action was a sham (in other words, objectively baseless). *See* Pet. App. 15a-36a (reviewing the "scope of the patent" rule and adhering to it in the present case); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (vacating similar FTC enforcement order), *cert. denied*, 548 U.S. 919 (2006); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003) (adopting the "scope of the patent" rule in rejecting antitrust challenge to Hatch-Waxman reverse-payment settlement), *cert. denied*, 543 U.S. 939 (2004). The Second and Federal Circuits have followed the Eleventh Circuit in applying the same "scope of the patent" rule to uphold Hatch-Waxman drug patent settlements. *See In re Tamoxifen Citrate*

Antitrust Litig., 466 F.3d 187, 212-13 (2d Cir. 2005), *cert. denied*, 551 U.S. 1144 (2007); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008), *cert. denied*, 557 U.S. 920 (2009).

SUMMARY OF ARGUMENT

This Court should affirm the "scope of the patent" rule applied by the court of appeals below. This rule properly recognizes and protects the full array of economic rights conferred under patent law, which necessarily include the right to settle non-sham patent litigation on any terms that stay within the presumptive exclusionary scope of the patent grant. The "scope of the patent" analysis is well established in this Court as the guiding principle for maintaining the line between the legitimate exercise of patent rights and the pro-competition requirements of antitrust law. It is the principle long applied in resolving antitrust challenges to restrictive terms in patent licenses, as well as claims that a patent holder has violated the antitrust laws by improperly pursuing an infringement action to protect its right to limited exclusivity. It is also the governing principle for application of the patent "misuse" doctrine, under which a patent used in committing an antitrust violation will be rendered unenforceable until the effects of the violation are dissipated.

The same rule appropriately applies to the patent holder's right to settle patent litigation. Unless the patent was procured by fraud or the underlying infringement suit is objectively baseless, the parties to patent litigation are free to structure settlements however they wish, provided the terms of the settlement do not purport to extend the exclusionary scope of the patent beyond its lawful term

or to suppress competition for technologies not claimed in the patent. A reverse payment by itself cannot be a basis for the forfeiture of patent rights. All patent settlements involve some transfer of value from the patent holder to the alleged infringer, and such reverse payments are fully consistent with and actually encouraged by the procedural framework of the Hatch-Waxman Act. Moreover, the freedom to settle patent litigation on terms within the scope of the patent is a form of property granted to the patent holder and protected by the Fifth Amendment of the Constitution. As the Founders declared in granting Congress the power to create a patent system, the firm preservation of these legal rights is the surest way to stimulate innovation and thus to maximize the long-run welfare of consumers. U.S. Const. Art. I, § 8, cl. 8.

The presumption of an antitrust violation promoted by the FTC would seriously interfere with the exercise of legitimate patent rights by rendering such exercise presumptively unlawful. The FTC's approach should be rejected because it will bring antitrust enforcement policy and patent law into direct, repeated, and unavoidable conflict. By penalizing and thus suppressing the exercise of the lawful rights held by the patentee, the FTC's enforcement policy would operate to the detriment of both patent law and competition policy and would only harm consumers in the end, contrary to the intent of Congress and to the principles enshrined in the Constitution.

ARGUMENT

THE "SCOPE OF THE PATENT" RULE SHOULD BE AFFIRMED BECAUSE IT CORRECTLY PRESERVES THE SPHERE OF ECONOMIC FREEDOM PROVIDED BY CONGRESS FOR THE RESOLUTION OF PATENT DISPUTES.

The FTC and its supporting *amici* urge the Court to view this case primarily through the lens of antitrust doctrine. They invoke the general antitrust principle presumptively condemning any agreement between potential competitors that prevents or limits competitive entry into the market, and they argue that this same principle should apply to create a presumption of an antitrust violation for "reverse payment" patent settlements. *See* Pet. Br. 20-24; *id.* at (I) (Question Presented) (citing *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 49-50 (1990) (per curiam)).[2] They maintain that giving priority to this antitrust policy would not unduly conflict with patent law because the patent holder will still retain the fallback ability to litigate the patent dispute to judgment (bearing the risk it might lose), an option specifically preserved by the Hatch-Waxman Act for branded drug makers. *See* Pet. Br. at 25-26.

With all respect, this argument has the analysis exactly backwards. The FTC's position ignores the full scope of the rights granted to the patent holder, including

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2. *See also* Br. for States as *Amici Curiae* in Support of Pet'r 10-18; Br. for 118 Law, Econ., & Bus. Profs., *et al.*, as *Amici Curiae* in Support of Pet'r 11-25; Br. for La. Wholesale Drug Co., *et al.*, as *Amici Curiae* in Support of Pet'r 13-17.

the sphere of economic freedom Congress intended for the resolution of patent litigation. The statutory rights granted with a patent establish a firm and clear zone of permissible activity where antitrust law has no application because antitrust liability would be incompatible with the full exercise of those rights. *See Simpson v. Union Oil Co.*, 377 U.S. 13, 24 (1964) ("The patent laws . . . are in *pari materia* with the antitrust laws and modify them *pro tanto*."). The theory behind the American system of patent law, as declared in the Constitution and supported by nearly 225 years of experience, is that the grant to inventors of exclusive and unrestricted rights to exploit their inventions for a limited period will benefit consumers and ultimately promote competition by encouraging and rewarding innovation. Nothing in the Hatch-Waxman Act reverses that fundamental premise in the context of drug patents.

Accordingly, the proper analysis should start from the perspective of patent law and should take care to preserve the full scope of rights granted with the patent. Unless the underlying patent litigation is shown to be a sham, or the patent was procured by fraud, any settlement terms that fall within the presumptive exclusionary scope of the patent should be free from antitrust scrutiny. The presumption of antitrust liability urged by the FTC cannot be squared with the intent of Congress and the principles embodied in the Constitution because it will seriously diminish the substantive property rights conferred by patent law. The firm maintenance of these legal rights is the surest means to promote invention and thereby to maximize competition and consumer welfare in the long run.

A. The Patent Act Confers on Patent Holders the Right to Settle Bona Fide Patent Disputes on Any Terms that Fall Within the Presumptive Exclusionary Scope of the Patent, Regardless of Whether Those Terms Include the Transfer of Value from the Patent Holder.

1. The Constitution declares that Congress is empowered "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the *exclusive Right* to their respective . . . Discoveries." U.S. Const. Art. I, § 8, cl. 8 (emphasis added). Congress has implemented that constitutional purpose through the Patent Act, codified at 35 U.S.C. §§ 1, *et seq.*, which confers on inventors the *exclusive right* to own, control, and profit from their innovations for a definite period of years. Thus, the defining attribute of a patent is "*the right to exclude others* from making, using, offering for sale, or selling the invention" claimed by the patent or, in the case of a process patent, the "products made by that process," for a period of years. 35 U.S.C. § 154(a)(1), (2) (emphasis added).

While patent law and antitrust law are both intended to benefit consumers by promoting innovation, they do so in very different and equally important ways. Antitrust doctrine protects consumers by *preserving competition*; patent law fosters invention and risk-taking by permitting the temporary *exclusion of competition* within specified limits. *See Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 221 (1980) ("The policy of free competition runs deep in our law. . . . But the policy of stimulating invention that underlies the entire patent system runs no less deep."). "The grant of a patent," in essence, "is the grant

of a statutory monopoly," *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 229 (1964), and "the essence of a patent grant is the right to exclude others from profiting by the patented invention," *Dawson Chem. Co.*, 448 U.S. at 215. The lawful monopoly and exclusionary rights granted to the patent holder imply a corresponding exemption from the demands of antitrust law, and this exemption necessarily mirrors and accommodates the full scope of those exclusionary rights.

2. The Patent Act reinforces the exclusionary nature of the patent by giving the patentee all legal rights necessary to enforce the grant of exclusivity against any person who would infringe the patent. The patent holder has the right to bring a civil action in court to enjoin the offending competition and may seek an award of damages to compensate for lost profits or other economic loss caused by the infringement. 35 U.S.C. §§ 281, 283, 284. This Court has held that an exercise of these legal rights by the patentee to enforce the exclusivity granted in the patent against would-be competitors can only be challenged under the antitrust laws where the enforcement action is a sham (objectively baseless) or where the patent was procured by fraud on the Patent and Trademark Office (and thus was never validly issued). *See Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 176-77 (1965); *Prof. Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 56-57 (1993); *Concrete Unlimited Inc. v. Cementcraft, Inc.*, 776 F.2d 1537, 1539 (Fed. Cir. 1985) (patent holder does not engage in unfair competition by "threatening alleged infringers with suit"), *cert. denied*, 479 U.S. 819 (1986).

This Court's recognition that the zealous exercise of patent rights is presumptively free from antitrust challenge, except in the narrow cases of sham litigation or patent fraud, is also supported by the presumption of patent validity mandated by Congress. The Patent Act declares that "[a] patent shall be presumed valid," and in any legal dispute, "[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." 35 U.S.C. § 282(a). This presumption of validity is not a mere "procedural device"; it imposes a "heightened standard of proof" against anyone challenging the exclusionary force of the patent that can only be overcome by clear and convincing evidence of invalidity. *Microsoft Corp. v. i4i Limited Partnership*, 564 U.S. ___, 131 S. Ct. 2238, 2246-47 (2011).

3. A patent also confers on the holder broad rights to license the patented technology to others on terms and conditions agreeable to the patent holder, or to refuse to license. *See* 35 U.S.C. § 271(d)(4)-(5); *cf. id.* § 261 (providing that a patentee may freely assign the patent "or any interest therein" to others). Provided the terms and conditions imposed by the patent holder do not purport to restrain competition beyond the exclusionary reach of the patent, the license will be free from antitrust challenge, even if it incorporates an agreement between actual or potential competitors that would constitute a naked restraint of trade in the absence of the patent.

Thus, patent licensing agreements may (and commonly do) include terms and conditions like price restrictions, territorial divisions, and other restraints on competition between the patent holder and the licensee that, if not for the patent, would be unlawful *per se* under the

Sherman Act (that is, in the absence of an efficiency-producing business integration). *See United States v. General Electric*, 272 U.S. at 488 (holding that antitrust law does not preclude a patentee from licensing patented technology to a competitor subject to a restriction on the price the competitor may charge for products made with the technology); *see also Simpson v. Union Oil Co.*, 377 U.S. at 23-24 (relying on *General Electric* to reaffirm a patent holder's right to license a patent on any terms and conditions that do not exceed the exclusionary scope of the patent); *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 704-05 (Fed. Cir. 1992) (same); *United States v. Westinghouse Elec. Corp.*, 648 F.2d 642, 647 (9th Cir. 1981) (holding that the government may not challenge territorial restrictions in patent licenses on the ground that they unreasonably stifle potential competition because applying antitrust law to licensing terms that fall within the exclusionary scope of the patents "would severely limit the protection extended by Congress in the [patent] laws").

4. The courts' established reliance on the "scope of the patent" principle to preserve the proper boundary between patent rights and antitrust liability is further demonstrated and underscored by cases applying the doctrine of patent "misuse." To wield a patent as leverage in the commission of an antitrust violation is patent misuse, which renders the patent unenforceable until the effects of the misuse are purged. *See Mallinckrodt*, 976 F.2d at 706, 708; *Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1001-02 (Fed. Cir.), *cert. denied*, 477 U.S. 905 (1986); *see also Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 491-93 (1942). But under this doctrine, there can be no patent misuse unless the patent holder

has acted "to expan[d] the patent beyond the legitimate scope of its monopoly." *Illinois Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 38, 41 (2006) (internal quotation marks and citations omitted); *see Princo Corp. v. ITC*, 616 F.3d 1318, 1328 (Fed. Cir. 2010) (en banc) ("[T]he key inquiry under the patent misuse doctrine is whether, by imposing the condition in question, the patentee has impermissibly broadened the physical or temporal scope of the patent grant and has done so in a manner that has anticompetitive effects. Where the patentee has not leveraged its patent beyond the scope of rights granted by the Patent Act, misuse has not been found.") (citations omitted), *cert. denied*, 131 S. Ct. 2480 (2011); *Mallinckrodt*, 976 F.2d at 708 ("Should the restriction [at issue] be found to be reasonably within the patent grant, *i.e.*, that it relates to subject matter within the scope of the patent claims, that ends the [misuse] inquiry.").

5. The foregoing discussion leads to a further conclusion about the patentee's statutory rights: The combination of the patent holder's express rights (i) to enforce the exclusivity granted in the patent through a civil action in court (35 U.S.C. §§ 281, 283, 284) and (ii) to agree to license the patent to would-be competitors on any terms and conditions that fall within the patent's exclusionary scope (*General Electric*, *supra*) necessarily implies that the Patent Act also protects the holder's right (iii) to settle bona fide patent litigation on any terms and conditions that do not restrain competition beyond the exclusionary sweep of the patent. The right to bring an infringement action in court implies the right to settle the litigation, including by granting a limited license of the patent rights; and the right to license the patent on any terms within the scope of the patent implies that a

license agreed to in a settlement may be conditioned on any terms of exchange, including "reverse payments," provided the agreement does not purport to extend the exclusion of competition to markets, technologies, parties, or time periods beyond what the full enforcement of the patent would allow.

Unless the underlying infringement claim is frivolous or the patent was obtained through fraud, settlement terms that fall within the outer bounds of the lawful monopoly held by the patentee are properly shielded, in accordance with the established "scope of the patent" principle, from "the hot coals of antitrust litigation," *Asahi Glass Co., Ltd. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 992 (N.D. Ill. 2003) (Posner, J., sitting by designation). Thus, this Court long ago held that "[w]here there are legitimately conflicting claims or threatened interferences [involving patents], a settlement by agreement, rather than litigation, *is not precluded by the [Sherman] Act.*" *Standard Oil Co. v. United States*, 283 U.S. 163, 171 (1931) (emphasis added).

The lawfulness (for antitrust purposes or otherwise) of patent settlement terms cannot turn on a prediction that the court in the underlying infringement litigation might not have upheld the full exclusionary scope of the patent. Any such analysis by a reviewing court is precluded by the statutory presumption of patent validity. A patentee that enjoys the statutory presumption "is entitled to defend the patent's validity in court, to sue alleged infringers, and to settle with them, whatever its private doubts" about the strength of its litigating position. *Asahi Glass Co.*, 289 F. Supp. 2d at 992-93. Unless the patent is fraudulent or the infringement claim a sham, it cannot be an antitrust

violation "to assert patent rights that one is not certain will be upheld in a suit . . . pressed to judgment and to settle the suit to avoid risking the loss of the rights. No one can be *certain* that he will prevail in a patent suit." *Id.* at 993 (emphasis in original).

6. Similarly, there is no legitimate basis, consistent with patent rights, to assume that a "reverse payment" in a patent settlement reflects an agreement to forestall competition "beyond the date that represents an otherwise reasonable litigation compromise." Pet. Br. at 34-35 (internal quotation marks omitted). Provided the agreed date of entry for the would-be competitor (the date when it is granted a license to use the patented technology) is no later than the end of the lawful patent term, the parties to the settlement are free to choose any date they wish, and the selection of the date is not subject to second judgment by an antitrust court (based on an assessment of the strength of the patent suit or otherwise).

The transfer of value from the patent holder to the would-be competitor, instead of the other way around, does not result in any forfeiture of statutory patent rights. The amount paid and the direction of the payment are terms of settlement that lie within the discretion of the settling parties; by themselves, such payment terms do not purport to extend the patent monopoly beyond its lawful bounds.

Moreover, every patent settlement in every context involves some transfer of value from the patent holder to the alleged infringer. *See Asahi Glass Co.*, 289 F. Supp. 2d at 994 ("*any* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not

settle unless he had something to show for the settlement") (emphasis in original). Settlement agreements are contracts, and all contracts require the exchange of consideration. *See* Restatement (Second) of Contracts § 17 (1981). Such "reverse" consideration may take various forms: A license with a favorable royalty rate, for example; a cross-licensing arrangement; the settlement of other disputes; the reimbursement of attorney's fees; the surrender of a claim for money damages; or compensation paid to the licensee for a later licensing date than was originally sought.

Given that the parties to a patent settlement have broad discretion to structure the mutual exchange of consideration as they see fit, the fact that some payment flows from the patent holder to the licensee cannot be sufficient to support a presumption of an antitrust violation. "[T]he exclusionary effect of the patent" is the only proper touchstone for determining whether the negotiated settlement is unlawful under the Sherman Act. *Valley Drug Co.*, 344 F.3d at 1306. *See Studiengeselschaft*, 670 F.2d at 1128 (conduct may be illegal under antitrust law "if it threatens competition in areas other than those protected by the patent"; if not, the conduct "*is otherwise legal*") (emphasis added); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981) ("where a patent has been lawfully acquired, subsequent conduct permissible under the patent laws cannot trigger any liability under the antitrust laws"), *cert. denied*, 455 U.S. 1016 (1982).

B. The Freedom to Settle Bona Fide Patent Disputes on Terms Falling Within the Exclusionary Scope of the Challenged Patent Also Finds Protection in the Constitution.

The Patent Act provides that patents "have the attributes of personal property." 35 U.S.C. § 261. The core right of the patent holder to exclude others from using the patented technology is "the very definition of 'property,'" *Schenck v. Nortron Corp.*, 713 F.2d 782, 786 n.3 (Fed. Cir. 1983), and this Court has long considered patents "a species of property," *Fl. Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank*, 527 U.S. 627, 642 (1999).

As with other property interests, patent rights are protected by the Fifth Amendment, and a patentee may not be deprived of those rights without due process of law. *Cedars-Sinai Med. Ctr. v. Watkins*, 11 F.3d 1573, 1582 (Fed. Cir. 1993), *cert. denied*, 512 U.S. 1235 (1994). These protected rights "necessarily includ[e] the right to license and exploit patents" as permitted by the Patent Act. *Id.* (internal quotation marks omitted). And this Court held nearly 90 years ago that they include the right to sue in court to recover for infringement. *See Richmond Screw Anchor Co. v. United States*, 275 U.S. 331, 345 (1928) (to take away a patent holder's right to recover for infringement would be tantamount to "tak[ing] away from a private citizen his lawful claim for damage to his property" and would raise serious Fifth Amendment concerns).

The same conclusion applies generally to the full range of legal rights granted with the patent. Because, as discussed above, the freedom to settle patent litigation

on any terms and conditions that fall within the scope of the patent springs from the right to enforce the patent in court and from the broad grant of discretion to "license and exploit" the patent however the patent holder wishes, *Cedars-Sinai*, 11 F.3d at 1582, this freedom, too, qualifies as a property right fully protected by the Fifth Amendment.

The protection guaranteed by the Due Process Clause provides a separate constitutional basis for this Court to conclude that the patent rights at issue here may not be stripped away merely on the basis of some administrative policy preference promoted by the FTC. At a minimum, where a government agency is claiming that some other statutory prohibition, such as the Sherman Act, creates a *per se* rule or presumption of unlawfulness that overrides one or more of the property rights conferred on the patent holder under the Patent Act, due process requires that the supervening statutory prohibition be clear and unavoidable. This Court has only accepted *per se* rules and presumed violations in antitrust enforcement based on long experience in the courts establishing that the particular challenged commercial arrangements have no valid purpose and no redeeming pro-competitive consequences. *See Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 886-87 (2007); *Business Elec. Corp. v. Sharp Elec. Corp.*, 485 U.S. 717, 723 (1988). The policy arguments offered by the FTC in support of the presumption advanced in this case do not come close to satisfying that standard and cannot overcome the protection for patent rights found in the Fifth Amendment.

C. Subjecting "Reverse Payment" Patent Settlements to the Presumption of Unlawfulness Advocated by the FTC Would Contradict the Intent of Congress by Substantially Interfering with the Exercise of Economic Freedom by Patent Litigants.

It follows from the preceding discussion that the presumption of an antitrust violation advanced by the FTC would substantially diminish the rights conferred with a patent. Patent litigants would inevitably suffer a significant loss of economic freedom in crafting settlement arrangements—a result that conflicts intolerably with the patent laws.

If the FTC's preferred enforcement policy were approved by this Court, no patent holder would enter into a patent settlement that involves a direct payment of money to the alleged infringer not specifically earmarked for litigation costs or as consideration for a separate, identified side-deal. Furthermore, the presumption of a violation would also substantially constrain the patent holder's willingness to enter into other forms of settlement that include non-monetary "reverse" transfers of value, and potentially any kind of licensing agreement, even outside the context of settlement, that arguably involves such a transfer.

In all of these cases, the patent holder would be highly reluctant to risk the possibility of running afoul of the FTC's presumption because of the dire consequences that would follow under the patent misuse doctrine, which holds that the illegal use of a patent as part of an antitrust violation will render the patent unenforceable, at least until

the competitive effects of the violation are fully dissipated or cured. *See Mallinckrodt*, 976 F.2d at 708. To render a patent unenforceable by operation of a presumption of an antitrust violation, particularly one founded on the FTC's assumption that the patent holder is unlikely to prevail in the underlying infringement litigation, would conflict head-on with the Patent Act's statutory presumption of patent validity, which requires that the full *potential* exclusionary scope of the patent be respected unless and until the party challenging the patent establishes its invalidity. *See* Pet. App. 19a-20a, 29a-30a. Thus, the FTC's position is tantamount to presuming the patent invalid or not infringed.

The chilling effect on patent settlements created by the FTC's presumption would be anathema to public policy. Patent settlements provide certainty and save valuable resources that firms can put to better use. The result advocated by the FTC would substantially alter the landscape in patent litigation, certainly in the Hatch-Waxman context but also potentially more broadly, by disrupting and dislocating patent rights and settlement options for patent litigants. The interference with established patent rights and practice that would follow should lead this Court to reject the FTC's approach. *See Int'l Wood Processors v. Power Dry, Inc.*, 792 F.2d 416, 427 (4th Cir. 1986) (holding that the application of antitrust law "to a specific patent-related practice" must be rejected where the introduction of antitrust sanctions "will frustrate the purposes of the patent laws").

D. Nothing in the Hatch-Waxman Act Negates the Settlement Rights of Patent Litigants or Otherwise Undermines the "Scope of the Patent" Rule Applied by the Eleventh Circuit.

In its recent decision accepting the FTC's proposed presumption of unlawfulness, the Third Circuit relied on the Hatch-Waxman Act as evidence that Congress intended to subject reverse-payment drug patent settlements to heightened antitrust scrutiny. *See In re K-Dur Antitrust Litig.*, 686 F.3d at 217-18. That conclusion is not warranted. The Hatch-Waxman Act was designed to address issues created by the drug approval process, to expedite approval for generic versions of established drugs, and to create a procedure for encouraging the timely resolution of patent disputes so that generic makers would have certainty as to when they could begin marketing generic drugs, but Hatch-Waxman did not reduce the substantive rights of holders of pioneer drug patents to settle litigation with generic makers over patent validity or infringement. In truth, the Hatch-Waxman Act is fully consistent with and supports the "scope of the patent" rule applied by the Eleventh Circuit.

1. Under Hatch-Waxman, a generic drug maker may file an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") for expedited approval of the bioequivalent form of a branded drug already approved for safety and efficacy. *See* 21 U.S.C. § 355(j). If the branded drug is protected by a patent and the generic maker desires to market its version of the drug before the patent expires, the generic maker must file a so-called "Paragraph IV certification," affirming that the patent is invalid or that it would not be infringed by the

manufacture, use, or sale of the generic equivalent. *Id.* § 355(j)(2)(A)(vii)(IV). The Hatch-Waxman Act provides that the holder of the branded drug patent must bring a patent infringement suit against the ANDA filer within 45 days of receiving the Paragraph IV certification in order to obtain a 30-month stay of FDA approval of the generic maker's ANDA. *Id.* § 355(j)(5)(B)(iii). In this manner, Hatch-Waxman strongly encourages the drug makers to resolve their patent dispute expeditiously, without reducing the term or substantive scope of the patent held by the branded drug maker.

2. Hatch-Waxman litigation, like other patent litigation, frequently ends with a settlement, but in the Hatch-Waxman conte.., "reverse payments are particularly to be expected ... because the Hatch-Waxman Act created an environment that encourages them." *In re Tamoxifen*, 466 F.3d at 206 (citation omitted); *see Schering-Plough*, 402 F.3d at 1074 (observing that Hatch-Waxman shifted the relative risks of the parties in a way that "explains the flows of settlement funds and their magnitude"). As the Second Circuit has explained, in a "typical patent infringement case" (outside the Hatch-Waxman context), "the alleged infringer enters the market ... after the investment of substantial sums of money for manufacturing, marketing, legal fees, and the like," and thus the risk of litigation weighs on the alleged infringer, since it may lose the value of its entire initial investment, in addition to paying money damages, if the patent holder prevails. *Tamoxifen*, 466 F.3d at 206. For that reason, the settlement of patent litigation often involves the payment of money by the alleged infringer to the patent holder. *See id.* Conversely, the Hatch-Waxman Act shifts the risk of litigation to the holder of the branded drug patent

by providing for the initiation of infringement litigation before the generic maker has incurred any significant costs in manufacturing, marketing, or selling the generic drug. The generic maker "has relatively little to lose in the litigation," whereas the holder of the branded drug patent has much to lose and little to gain from pressing the litigation to judgment, and this dynamic creates a strong incentive for reverse-payment patent settlements under Hatch-Waxman. *Id.* at 207.

3. The "scope of the patent" rule appropriately accommodates the reversal of incentives created by the Hatch-Waxman Act while taking care to protect substantive patent rights. In doing so, this rule actually promotes competition from generic drug makers by preserving the freedom of the parties to settle their patent dispute in a manner that permits entry by the generic maker on a date certain before expiration of the branded maker's patent. On the other hand, by significantly constraining the settlement options available to the drug makers, the FTC's presumption of unlawfulness for reverse-payment settlements would create a disincentive for generic makers to challenge the pioneer patent in the first place by suppressing the generic's prospects for obtaining an advantageous settlement, and it would therefore end up reducing the availability of low-cost generic drugs for consumers. *See Asahi Glass*, 289 F. Supp. 2d at 994 ("A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive."); *see also Schering-Plough*, 402 F.3d at 1075 (concluding that reverse-payment settlements "benefit the public by introducing a new rival

into the market, facilitating competitive production, and encouraging further innovation"). Such an anticompetitive result runs directly against both the goals of antitrust policy and the purposes of the Hatch-Waxman scheme.

4. Contrary to the suggestions of the FTC's *amici*,[3] the legislative history of the Hatch-Waxman Act provides no support for the FTC's position. It only confirms that Congress did not intend to cut short the term of the branded drug patent or diminish the substantive patent settlement rights of the holder in enacting the Hatch-Waxman framework.

Hatch-Waxman was designed to address anomalies created by the interaction between patent law and the FDA's new drug approval process, and in so doing, the legislation reflected a compromise that provided benefits to both branded and generic manufacturers. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669-71 (1990). First, the legislation permitted term extensions of up to five years for owners of pioneer patents to compensate for the delay in the initial marketing of the patented product caused by the FDA approval process. *See* 35 U.S.C. § 156. In this way, the act benefited the branded maker by correcting a costly regulatory distortion that was occurring at the front end of the patent term. *See Eli Lilly*, 496 U.S. at 669-70. Second, the legislation also corrected a regulatory distortion at the back end of the patent term that was effectively giving the patent holder a *de facto* extension of the patent term at the expense of

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3. *See* Br. for Rep. Henry A. Waxman as *Amicus Curiae* in Support of Pet'r 11-14; Br. for Nat'l Ass'n of Chain Drug Stores as *Amicus Curiae* in Support of Pet'r 15-22.

the generic maker: It did this by establishing an expedited approval process (the ANDA process) for bioequivalent generic drugs that could begin before the expiration of the branded drug patent, and by providing a safe harbor from patent infringement liability that permitted the generic maker to engage in the research, development, and manufacture of the bioequivalent drug required for early ANDA approval. *See* 21 U.S.C. § 355(j); 35 U.S.C. § 271(e)(1); *Eli Lilly*, 496 U.S. at 670-71. Finally, the legislation established the Paragraph IV certification procedure and the patent litigation-stay framework for prompting an early resolution of the inevitable patent disputes between the branded and generic makers, so that the generic maker would have certainty that it could begin marketing the generic drug no later than the date when the branded drug patent expired. *See* 21 U.S.C. §§ 355(j)(2)A)(vii), 355(j)(5)(B)(iii); H.R. Rep. No. 857 pt. 1, at 27, 98th Cong., 2d Sess. (1984) ("House Rep. pt. 1") ("some ANDA's will be submitted and ready for approval before the patent on the listed drug has expired," and the Paragraph IV procedural framework thus "permits the commencement of a legal action for patent infringement before the generic drug maker has begun marketing").

The legislative history is quite clear that in crafting this litigation framework, Congress did not intend to diminish in any way the substantive patent rights of the branded drug maker. The principal committee report accompanying the legislation stated that this framework "fairly balances the rights of a patent owner to prevent others from making, using, or selling its patented product and the rights of third parties to contest the validity of a patent or to market a product which they believe is not

claimed by the patent." House Rep. pt. 1, at 27. *See id.* at 28 (emphasis added):

> The provisions of this bill relating to the litigation of disputes involving patent validity and infringement are *not intended to modify existing patent law* with respect to the burden of proof and the nature of the proof to be considered by the courts in determining whether a patent is valid or infringed. . . . [A] patent would have the same statutory presumption of validity as is afforded under current law.

Thus, the chief sponsor of the legislation, Rep. Waxman, specifically explained that it was the purpose and effect of the Hatch-Waxman Act compromise to give the branded maker extra patent protection to cover the time needed for upfront research and development while giving the generic maker the opportunity to market the generic drug *after the expiration* of any blocking patent held by the branded maker, *not* to reduce in any way the term of the patent or the rights of the branded patent holder to enforce its patent and prevent the early marketing of the generic drug. *See* Cong. Rec. H9118 (Sept. 6, 1984) (statement of Rep. Waxman) (emphasis added):

> [T]he whole conceptuality of this bill is to give more time for the firm developing the patented drug, to give them further incentive for research and development. There is public good in that. The other side of it is to give the

> opportunity for competition in generic drugs to be on the market *after that patent has expired.*[4]

In sum, the Hatch-Waxman scheme was never intended to override the drug patent holder's basic patent-law right to settle infringement litigation with the generic on any terms falling within the exclusionary scope of the patent, whether or not those terms include a "reverse payment" to the generic maker.

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4. Nor did Congress mandate an antitrust prohibition on reverse-payment drug patent settlements in the later Hatch-Waxman amendments made by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, 117 Stat. 2066. In relevant part, the MMA amendments to Hatch-Waxman required that patent settlements between branded and generic drug makers be submitted to the FTC and the Justice Department for antitrust review and provided that the generic maker would forfeit its priority rights under Hatch-Waxman if the settlement were found to violate the antitrust laws or the FTC Act. MMA §§ 1102, 1111-1118, 117 Stat. 2458-59, 2461-64, *codified at* 21 U.S.C. §§ 355(j)(5)(D), 355 note. Contrary to the suggestion of *amici*, *see* Br. for Rep. Henry A. Waxman as *Amicus Curiae* 14-19, the review process added by the MMA does not evidence any conclusion by Congress one way or the other concerning the appropriate outcome of the agency's antitrust review.

CONCLUSION

For the foregoing reasons, *amicus curiae* the American Intellectual Property Law Association urges the Court to affirm the judgment of the court of appeals.

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AMICUS CURIAE BRIEF

RECORD AND BRIEFS

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FEDERAL TRADE COMMISSION,

Petitioner,

v.

WATSON PHARMACEUTICALS, INC., *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

AMICUS CURIAE BRIEF OF AMERICA'S HEALTH INSURANCE PLANS IN SUPPORT OF PETITIONER

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Amicus Curiae America's Health Insurance Plans ("AHIP" or "*Amicus*") respectfully submits this brief in support of Petitioner, The Federal Trade Commission ("FTC").

AMICUS' INTEREST IN THIS CASE[1]

AHIP is the national association representing the health insurance industry. AHIP's members provide health and supplemental benefits to more than 200 million Americans through employer-sponsored coverage, the individual insurance market and public programs such as Medicare and Medicaid. AHIP advocates for public policies that expand access to affordable health care through a competitive marketplace that fosters choice, quality and innovation.

In 2011, health insurers paid more than $214 billion for prescription drugs dispensed to beneficiaries of prescription drug benefit plans. www.cms.hhs.gov/nationalhealthexpenddata/. *Amicus'* members have a strong interest in a competitive market for prescription drugs, in which the availability of generic versions of brand-name drugs is unrestrained by agreements that artificially prolong brand drug market power past the

1. Under Rule 37.6, counsel certifies that no party, or counsel for a party, authored or paid for this brief in whole or in part, or made a monetary contribution intended to fund its preparation or submission. No person other than *Amicus*, its members and their counsel made a monetary contribution to the brief. The FTC has provided blanket consent to the filing of *amicus* briefs in a letter filed with the Court on December 20, 2012. Counsel of Record for all Respondents have provided their written consent to this filing and such consents are being submitted herewith.

time intended by Congress. The most insidious and economically damaging of these artifices is when brand drug manufacturers pay generic manufacturers to delay competing, generally under the guise of settlement of patent lawsuits. A 2010 FTC study estimated that such settlements increase the cost of U.S. prescription drug expense by $3.5 billion annually, with the lion's share of that borne by health benefit plans and their customers. PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS: A FEDERAL TRADE COMMISSION STAFF STUDY, at 2 (Jan. 2010), available at http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf. For the 2012 fiscal year (from October 2011 to September 2012), FTC's Bureau of Competition identified 40 such settlements where brand drug manufacturers paid would-be competitors to delay selling generic versions of 31 different brand-name drugs whose fiscal 2012 U.S. sales exceeded $8.0 billion. AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF AGREEMENTS FILED IN FY 2012: A REPORT BY THE BUREAU OF COMPETITION (Jan. 17, 2013), available at http://www.ftc.gov/os/2013/01/130117mmareport.pdf.

SUMMARY OF ARGUMENT

The FTC has prosecuted several actions under Section 5 of the Federal Trade Commission Act focusing on the potential harm to consumers and to competition generally posed by these agreements. *Amicus* wishes to communicate to the Court that such "pay-for-delay" reverse payment settlements harm health insurers and other third party payers such as self-funded employer sponsored ERISA plans, and those who receive their coverage from such insurers and plans.

ARGUMENT

I. Third Party Payers Bear The Vast Majority of the Adverse Economic Impact of "Pay-For-Delay" Agreements.

A. The Economics of U.S. Retail Prescription Drug Transactions.

A prescription drug is typically sold in capsule, tablet, gel, or injection form through a distribution chain of manufacturer to wholesalers to retail pharmacy, which delivers the product to the consumer. Prescription drugs usually pass in unaltered form through the chain from manufacturer to user. This is the case with Androgel, a testosterone gel.

A minority of consumers have no third party payer prescription drug insurance benefits and pay cash out of pocket at the pharmacy counter. However, a majority of Americans have private or government sponsored prescription drug reimbursement coverage or insurance, making the "consumer" for economic purposes a dual end-payer consisting of the individual benefit plan member and his or her third party payer (for simplicity this brief refers to these benefit plans with the more common parlance as "insurance" although some plans may have other than insured funding sources, such as self-funded ERISA plans). According to U.S. Census Bureau statistics for 2011, 63.9 percent of U.S. citizens had third party payer health benefits. INCOME, POVERTY AND HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2011, at 21 (Sep. 2012), available at http://www.census.gov/prod/2012pubs/p60-243.pdf.

Virtually all United States pharmacies have contracts with third party payers. Pursuant to these contracts, pharmacies typically charge the dual end-payer (the third party payer or insurer and the benefit plan member or insured), a retail price based on a percentage of pricing benchmark, plus a dispensing fee of a few dollars per prescription. The pharmacies generally collect a co-payment (or deductible) from the insured patient and charge the balance to the third party payer. These charges are generally determined electronically and instantaneously at the retail pharmacy counter (or by mail order pharmacies) through computer interfaces whereby a patient's benefit terms are verified, the third party payer is billed, and the co-payment is collected from the patient.

After a generic bioequivalent of a branded drug is approved by the FDA and made available by its manufacturer, third party payers' contracts with pharmacies and members typically reduce the amount third party payers will pay pharmacies for either version (brand or generic) of the drug using a pricing benchmark based upon the lower price of the generic drug. Following the Hatch-Waxman Act's 180-day period of marketing exclusivity granted to the first-filed generic company, later-filed generic companies typically offer the drug for even lower prices, and third party payer pharmacy contracts customarily contain pricing mechanisms that then further reduce how much they will pay for any version of the drug. *See* PREPARED STATEMENT OF THE FEDERAL TRADE COMMISSION BEFORE THE SPECIAL COMMITTEE ON AGING OF THE UNITED STATES SENATE ON BARRIERS TO GENERIC ENTRY, at 2, 6, 10 (July 20, 2006), available at http://www.ftc.gov/os/2006/07/P052103BarrierstoGenericEntryTestimonySenate07202006.pdf; PAY-FOR-DELAY:

HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS, FTC STAFF STUDY, at 8 (Jan. 2010), available at http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.

After generic versions of a prescription drug are available, a typical insured patient has a choice. He can either accept the lower-priced generic (for which he generally pays a lower co-payment, sharing with his insurer the benefit of the drug's lower price) or choose to pay more out of his pocket to buy the brand version of the drug. Consumers usually accept the lower priced generic, resulting in cost-savings for both the patient and his third party payer. "Publicly available information about generic drug launches suggests that a generic market typically matures about one year after the first entrant comes on the market," with "pharmacists fill[ing] 90 of every 100 prescriptions for the molecule with an AB-rated . . . generic." PAY-FOR-DELAY, *supra*, at 8.

B. The Rising Costs of Prescription Drugs.

The Centers for Medicare and Medicaid ("CMS") estimate that for calendar year 2009, total prescription drug expenditures were approximately $254.5 billion, with private health insurance paying 46.44% (approximately $118.2 billion), patient out-of-pocket cash payments comprising 19.48% (approximately $49.6 billion), CMS payments comprising 29.8% (approximately $75.9 billion) and miscellaneous other private, state and federal programs accounting for the remainder. NATIONAL HEALTH EXPENDITURES BY TYPE OF SERVICE AND SOURCE OF FUNDS: CALENDAR YEARS 1960 TO 2011: CMS STUDY, available at http://www.cms.hhs.gov/nationalhealthexpenddata/. Total prescription drug expenditures rose to approximately

$263 billion in 2011, with private health insurance paying 46.42% ($122.1 billion), patient out-of-pocket cash payments representing 17.14% ($45 billion), and CMS payments representing approximately 32% ($84.23 billion). Prescription drug costs represented approximately 10% of total national healthcare expenditures for the calendar years 2009-2011. *Id.*

C. Cost Savings From Generic Use.

In January of 2012, The United States Government Accountability Office collected studies of cost savings estimates as a result of generic drug use. DRUG PRICING: RESEARCH ON SAVINGS FROM GENERIC DRUG USE: GAO STUDY (Jan. 31, 2012), available at http://www.gao.gov/assets/590/588064.pdf. While these studies varied in scope and end points, each concluded that wider use of generic pharmaceuticals resulted in health care savings. The GAO reported these studies' findings as including: (1) generic substitution "has saved the U.S. health care system more than $1 trillion" during the 12-year period of 1999 to 2010; and (2) "dispensing generic drugs rather than their brand-name counterparts reduced total Part D prescription drug costs in 2007 by about $33 billion," with $9 billion of these savings accruing to enrollees. *Id.* Hence, the health care system achieves tremendous cost savings with generic drugs.

CONCLUSION

Amicus encourages the Court to recognize the significant economic impact reverse-payment settlements like the one under review have on its members, those who receive coverage through its members, and the United States healthcare system.

Respectfully submitted,

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AMICUS CURIAE BRIEF

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IN THE

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—v.—

ACTAVIS, INC., ET AL.,

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INTEREST OF THE *AMICI CURIAE*

Amici curiae are economists who teach at leading colleges and universities throughout the United States and consultants who specialize in the economics of the pharmaceutical industry. (A list of the *amici curiae* is attached as Appendix A.) *Amici* have written extensively in the field of economics, including industrial organization, competition, and antitrust economics and policy. They write to bring to the Court's attention economic analysis relevant to determining the appropriate antitrust standard for evaluating patent dispute settlement agreements in which a pharmaceutical patent owner makes a payment to a potential generic competitor.

Amici believe that the available economic evidence does not adequately support Petitioner's contention that "reverse payment" settlement agreements must be presumptively illegal, and that Petitioner's approach threatens to disrupt a competitive market that serves both consumers' short and long term interests. For these reasons, *amici* believe that this Court should reject Petitioner's request to treat "reverse payment" settlements as presumptively illegal.[1]

SUMMARY OF ARGUMENT

Citing harm to consumer welfare, Petitioner contends that this Court should adopt a standard by which "reverse payment" patent settlements will be

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[1] The parties have consented to the filing of this brief. *Amici* and their counsel have authored the entirety of this brief, and no person or entity has made a monetary contribution to its preparation or submission.

presumptively unlawful, notwithstanding whether the patent holder had a good faith basis to petition a court to protect its presumptively lawful patent exclusivity rights and subsequently entered into an arm's length settlement with the challenger. Economic evidence does not support this Court's adoption of the approach Petitioner proposes.

Ample economic evidence documents that pharmaceutical innovation produces significant consumer benefits. Pharmaceutical innovation provides major improvements in the standard of living, and acts as an important driver of economic growth. The patent system provides economic incentives that reward the high-risk, capital-intensive investments necessary to produce innovations in this market. Through existing regulations, policymakers have addressed the need to encourage and protect innovation and the dynamic efficiencies it produces while simultaneously promoting utilization of generic drugs and the static efficiencies they produce.

For example, the Hatch-Waxman Act reflects Congress's effort to balance incentives for researching and developing new pharmaceutical products with consumers' interest in accessing the existing stock of drugs. It provides additional protections for drug patents, while providing incentives for generic companies to challenge brand patents. Contrary to Petitioner's contention, reverse payments have not altered the balance policymakers sought to achieve. Generic drug utilization—driven in part by challenges to pharmaceutical patents and settlements resolving those challenges—is at a historically high level. Moreover, reverse payment settlements account for only a fraction of all

pharmaceutical patent settlements and typically allow for generic entry many years prior to patent expiration. Reverse payments have not led to an increase in the length of market exclusivity for brand-name drugs, as would be expected if such settlements altered the balance between dynamic and static efficiencies. Thus, Petitioner's suggestion that the Hatch-Waxman Act and current market dynamics are not sufficiently promoting generic utilization does not withstand scrutiny.

Reverse payments in patent settlements can occur for a variety of reasons having nothing to do with payment for delaying entry. For example, reverse payments may be necessary for the parties to reach a settlement in cases where a generic company's high discount rate makes it unwilling to settle with a long wait until entry. They may also be necessary for brand companies to overcome bargaining disadvantages caused by risk aversion. Brand companies are likely to be more risk averse than their generic challengers because they usually have significantly more to lose from a negative trial outcome. In contrast, generic companies are generally not at risk for damages and risk only litigation costs. A settlement with a reverse payment therefore cannot necessarily be replaced with a different settlement enabling earlier generic entry as opposed to continuing litigation.

The data and analysis on which Petitioner relies to show that reverse payment settlements harm consumers do not provide support for a standard of presumptive illegality. Petitioner's failure to identify a defensible definition of "reverse payment" settlements undermines its analysis. For the purposes of its economic analysis, Petitioner defines

a "reverse payment" settlement as any settlement that involves a component other than a negotiated entry date. This definition sweeps in many agreements that do not have any net payment from a patent holder to a generic challenger. Moreover, because settlements that actually involve net payments from the brand to the generic are not economically different from many patent settlements seen outside the pharmaceutical industry, applying a presumptive illegality standard to even this narrower universe of settlements could have far reaching effects well beyond pharmaceutical industry patent cases.

Petitioner's analyses of (1) the percentage of patent cases that generics won, and (2) the exclusion period associated with "reverse payment" patent settlements are inaccurate and misleading. For example, contrary to Petitioner's assumption, the outcome of litigation is not sufficiently predictable that the presence of a reverse payment presumptively demonstrates harm. Neither economists nor litigants possess such predictive powers, and certainly not to a degree that would justify imposing added costs on litigants and shifting the current balance between dynamic and static efficiencies.

Petitioner's economic evidence does not support its contention that this Court's adoption of a standard by which "reverse payment" patent settlements will be presumptively unlawful would benefit consumer welfare. In fact, the economic evidence weighs against the adoption of such a standard.

ARGUMENT

A. Pharmaceutical Innovation Drives Consumer Well-Being

Consumers benefit both from efforts to develop new products—dynamic efficiency—and from improved access to lower priced versions of existing products—static efficiency.[2] Dynamic efficiencies attributable to innovation in health and pharmaceuticals are a major cause of improved standards of living over the last century. *See* Mark A. Lemley, *Industry-Specific Antitrust Policy for Innovation*, 2011 Colum. Bus. L. Rev. 637, 638–39 (2011) [Lemley, *Antitrust Policy for Innovation*] ("Think for a moment about whether static or dynamic efficiency is a more important driver of our economy, and the answer will be obvious. We benefit from market competition between existing products, but we benefit far more from the development of new products.") Economic analysis shows that innovative pharmaceuticals have been responsible for much of the increase in U.S. life expectancy[3] and the reduction in infant mortality over the past decades.[4]

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[2] Static efficiency concerns the optimal use of current resources (*e.g.*, drugs already developed) to maximize short-run welfare, while dynamic efficiency balances static efficiency with incentives to develop new resources (*e.g.*, new drug development) over the long run.

[3] *See* Frank R. Lichtenberg, *Sources of the U.S. Longevity Increase, 1960-2001*, 44 Q. Rev. Econ. & Fin. 369, 369 (2004); Frank R. Lichtenberg, *The Impact of New Drugs on US Longevity and Medical Expenditure, 1990-2003: Evidence from Longitudinal, Disease-Level Data*, 97 Am. Econ. Rev. 438, 442 (May 2007).

[4] Pierre-Yves Crémieux, et al., *Pharmaceutical Spending and Health Outcomes in the United States, in Investing in*

Economic studies of particular drug classes indicate that societal returns to pharmaceutical development are large. For example, a study of HIV/AIDS drugs showed that every dollar spent paying for such drugs benefited society by approximately $19 dollars. Tomas Philipson & Anupam B. Jena, *Who Benefits from New Medical Technologies? Estimates of Consumer and Producer Surpluses for HIV/AIDS Drugs* (Nat'l Bureau Econ. Research, Working Paper No. 11810 at 3–4, 2005) (published in *Forum for Health Economics and Policy: Biomedical Research and the Economy* (2005)). Another study of statins found that the benefits of statin use in terms of reduced hospitalizations and increased life expectancy were four times the costs. *See* David C. Grabowski, et al., *The Large Social Value Resulting From Use Of Statins Warrants Steps To Improve Adherence And Broaden Treatment*, 31 Health Aff. 2276, 2280 (2012).

Pharmaceutical research has also been found to be more effective in delivering benefits to consumers than other medical expenditures. For example, one study's results indicate that, while approximately $9,640 in medical expenditures is required to gain one life-year, only $926 in pharmaceutical research and development is needed to yield the same benefit. Frank Lichtenberg, *Sources of the U.S. Longevity Increase, 1960–2001*, 44 Q. Rev. Econ. & Fin. 369, 369 (2004). Results from another study also show that substituting new drugs for older drugs leads to significant improvements in patient health. Frank

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Health: The Social and Economic Benefits of Health Care Innovation 59, 68 (I. Farquar, K. Summers & A. Sorkin eds., 2001)

R. Lichtenberg, *Are the Benefits of Newer Drugs Worth Their Cost? Evidence from the 1996 MEPS*, 20 Health Aff. 241, 241–245 (Sept./Oct. 2001).

Economic research has found that increased life expectancy and health have produced gains in Americans' well-being as important as those from increases in material abundance. *See* Kevin M. Murphy & Robert H. Topel, *The Value of Health and Longevity*, 114 J. Pol. Econ. 871, 872, 902 (2006); William D. Nordhaus, *Irving Fisher and the Contribution of Improved Longevity to Living Standards*, 64 Am. J. Econ. & Soc. 367, 367–68, 382-90 (Jan. 2005). An economic study found that the increase in life expectancy over the past century has provided a representative American the equivalent of over $1.2 million in value. Murphy & Topel, *The Value of Health and Longevity*, 114 J. Pol. Econ. at 871-72.

The average cost to develop and bring to market a single FDA-approved prescription drug (including the cost of development failures) was estimated at over $1.3 billion in 2007. *See* Joseph A. DiMasi & Henry G. Grabowski, *The Costs of Biopharmaceutical R&D: Is Biotech Different?*, 28 Managerial & Decision Econ. 469, 469 (2007). By contrast, FDA estimates that it costs a generic firm between $300,000 and one million dollars to prepare and submit an abbreviated new drug application ("ANDA"). Requirements for Submission of In Vivo Bioequivalence Data; Proposed Rule, 68 Fed. Reg. 61,640, 61,645 (Oct. 29, 2003). Even *amici* writing in support of Petitioner have recognized these disparities. *See* Lemley, *Antitrust Policy for Innovation*, 2011 Colum. Bus. L. Rev. at 641–43 ("Pharmaceutical innovation is notoriously expensive

and time-consuming. . . . Although imitation of a drug is reasonably costly in absolute terms, a generic manufacturer that can prove bioequivalency can avoid almost all of the R&D cost and can get FDA approval much more quickly than the original manufacturer.").

The economic risks associated with pharmaceutical research and development are widely recognized. FDA ultimately approves for sale as few as one in ten thousand compounds that enter preclinical testing.[5] Patent protection allows brand companies to recoup these high-risk investments and thereby provides incentives to make such large investments. *See* Lemley, *Antitrust Policy for Innovation*, 2011 Colum. Bus. L. Rev. at 643 ("[I]t is likely that innovation would drop substantially in the pharmaceutical industry in the absence of effective patent protection. Indeed, a wealth of empirical evidence finds that patents are extremely important to innovation in pharmaceuticals.").

If patent protection were removed or lessened, or if settlement restrictions reduced patent value, decreases in dynamic efficiency (innovation) would likely more than offset the supposed short-term gains from access to generic drugs on which Petitioner focuses. Indeed, one economic study analyzed the effects of eliminating drug patents and found that the reduced flow of new therapies would cause consumer losses three times the short-term gains

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[5] Martin S. Lipsky, & Lisa K. Sharp, *From Idea to Market: The Drug Approval Process*, 14 J. Am. Board Fam. Pract. 362, 364 (2001) ("For approximately every 5,000 to 10,000 compounds that enter preclinical testing, only one is approved for marketing.").

from immediate generic competition on all drugs. James W. Hughes, Michael J. Moore & Edward A. Snyder, *Napsterizing Pharmaceuticals: Access, Innovation, and Welfare* (Working Paper at 3, 15–16, Jan. 2011).

Petitioner's analysis of consumer welfare largely ignores the value of innovation and the potential adverse impact Petitioner's presumptive illegality standard would have on the dynamic efficiencies innovation provides to consumers.

B. The Hatch-Waxman Act Carefully Balances Access to Generic Drugs and Innovation

Policymakers recognize that promoting innovation with the potential for a period of exclusivity is inherently at odds with the competing benefits of allowing the largest number of entities to compete in a given market. Congress has addressed this trade-off in the pharmaceutical sector, most notably through the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (the "Hatch-Waxman Act").

The Hatch-Waxman Act balances incentives for innovative efforts that result in new pharmaceutical products against enhanced access to existing products through generic drugs.

In economic terms, the Hatch-Waxman Act addresses the tradeoff between dynamic efficiency and static efficiency. As Congressman Henry Waxman stated: "The law that became known as Hatch-Waxman represented a careful balance between access and innovation. Because both are vitally necessary to our nation's health." Henry A. Waxman, Speech: Rep. Waxman Delivered a Speech

to the Generic Pharmaceutical Association (Jan. 28, 2003), *available at* http://waxman.house.gov/speech-rep-waxman-delivered-speech-generic-pharmaceutical-association. The Hatch-Waxman Act (i) reduced the cost of generic entry by relieving generic manufacturers of the burden of proving that their drugs are safe and effective as opposed to biologically equivalent to the related brand pharmaceutical, *see* 21 U.S.C. § 355(j); (ii) effectively granted generic manufacturers royalty-free licenses to use patented drugs to perform bioequivalency testing, *see* 35 U.S.C. § 271(e)(1); and (iii) provided a framework to encourage and facilitate challenges to patents covering brand pharmaceuticals, *see* 21 U.S.C. § 355(b), (j). In addition, as discussed below, the Hatch-Waxman Act allows generic manufacturers to challenge a patent without entering the market and risking damage exposure.

To achieve a socially desirable balance, the Hatch-Waxman Act included measures to lengthen the effective patent life of innovative pharmaceuticals and thereby increase the development of new drugs. For example, the Act extends the life of one patent for each drug by up to five years to take into account some of the patent life lost during the lengthy drug testing and approval process. *See* 35 U.S.C. § 156. The Act also provides an automatic 30-month stay of generic approval when a brand company sues a generic challenger, permitting the patent holder time to enforce its intellectual property rights. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(II). If the patent holder prevails in the patent litigation, the Act provides for an automatic injunction barring approval of the generic challenger. *See* 35 U.S.C. § 271(e)(4)(A) (2000).

Thus, while encouraging generic access, the Act also protects innovation and the companies engaged in high-stakes investments in pharmaceutical research and development.

1. Quantifying the Impact of Hatch-Waxman on Access to Generics

Petitioner's suggestion that the Hatch-Waxman Act and current market dynamics are not sufficiently promoting generic utilization does not withstand scrutiny. Under the Hatch-Waxman regime, use of generic drugs is at an all-time high. The Hatch-Waxman Act has been extremely successful at facilitating generic entry, thereby achieving lower drug prices for consumers. *See* Ernst R. Berndt & Murray L. Aitken, *Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century after the 1984 Waxman-Hatch Legislation*, 18 Int'l J. Econ. Bus. 177, 177–78, 181–198 (2011).[6] Over time, the share of generics in the marketplace has increased dramatically. *See* Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 New Eng. J. Med. 1993, 1993–6 (2007). When Hatch-Waxman was enacted in 1984, generic drugs accounted for 19 percent of all U.S. prescriptions; by 2001 generic usage rose to 47 percent. FTC, *Generic Drug Entry Prior to Patent Expiration* at 3

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[6] *See also* Ernst R. Berndt, *Pharmaceuticals in U.S. Health Care: Determinants of Quantity and Price*, 16 J. Econ. Persp. No. 4, 45, 62–63 (2002).

(July 2002), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf. The increase has been more rapid in recent years. As of 2011, generic usage stood at 80 percent, a fourfold increase since Hatch-Waxman was enacted. IMS Institute for Healthcare Informatics, *The Use of Medicines in the United States: Review of 2011* at 26 (Apr. 2012) http://www.imshealth.com/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/IHII_Medicines_in_U.S_Report_2011.pdf.

Legislative efforts to increase the incentives for generic companies to challenge brand-name drug patents have contributed to this increase. Unlike other industries, generic manufacturers can develop a generic pharmaceutical and pursue FDA approval without the patent holder having the ability to challenge that conduct as violating its intellectual property rights. *See* 35 U.S.C. § 271(e)(1). The generic company can then challenge the validity of the patent just by applying for FDA approval. Thus, generic challengers do not have to enter the market and expose themselves to damages.[7] *See* 21 U.S.C. § 355(j); Stephanie Greene, *A Prescription for Change: How the Medicare Act Revises Hatch-Waxman to Speed Market Entry of Generic Drugs*, 30 J. Corp. L. 309, 316–17 (2005) [Greene, *A Prescription for Change*]. Generic companies rarely risk exposure to patent damages by attempting to launch products prior to resolving the underlying patent litigation. Further, the first generic challenger (or in some cases

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[7] In other industries, many potential patent infringers may never choose to challenge a patent because of the risk of damages.

challengers) may obtain a 180-day period of generic market exclusivity. FDA, *Guidance for Industry: 180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day*, http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072851.pdf.

Consistent with Congress's policy objective, in recent years there has been an overall increase in pharmaceutical patent challenges, as well as a sharper increase in challenges soon after initial approval of the brand-name drug. *See, e.g.*, C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. Health Econ. 327, 327–28 (2012); Henry G. Grabowski & Margaret Kyle, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 Managerial & Decision Econ. 491, 492, 495-96, 501 (2007) [Grabowski & Kyle, *Generic Competition and Market Exclusivity Periods*]. The low costs and large incentives to challenge patents, combined with the unpredictable and imperfect nature of litigation and the lack of damage exposure, encourage generic firms to challenge patents without regard to the likelihood of prevailing. *See generally* Grabowski & Kyle, *Generic Competition and Market Exclusivity Periods*.[8]

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[8] *See also* Kelly Smith & Jonathan Gleklen, *Generic Drugmakers Will Challenge Patents Even When They Have a 97% Chance of Losing: The FTC Report that K-Dur Ignored*, CPI Antitrust Chron. (Sept. 2012 (2)); C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents*, 8 J. Empirical Legal Stud. 613, 624, 626 (2011) (showing a rise in the rate of challenges to "new chemical entity," drugs with novel active ingredients); Martin A. Voet, *The Generic Challenge:*

While generic competition lowers drug prices, the prevalence of prescription benefit plans whereby consumers pay a "co-payment" for their prescription drugs diminishes any concerns about underutilization of drugs that do not have generic equivalents. *See* Kaiser Family Foundation, *Prescription Drug Trends* at 5 (May 2010), http://www.kff.org/rxdrugs/upload/3057-08.pdf. The vast majority of consumers can access brand-name drugs for amounts substantially below list prices (generally below $50 per prescription). With the passage of the Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119 (2010), the percentage of U.S. citizens with prescription drug benefits will increase yet further. *Id.* at 5–6.

2. The Use of Reverse Payments in the Context of the Hatch-Waxman Act

Petitioner contends that "reverse payment" settlements must be treated as presumptively illegal to protect consumers. However, the available economic evidence does not support Petitioner's theory that use of "reverse payments" has altered the balance between dynamic and static efficiencies that policymakers sought to achieve. A large portion of the increase in the availability and use of generic drugs, as demonstrated above, has occurred alongside the use of "reverse payments."

Indeed, the use of reverse payments has not displaced the incentive for multiple generics to submit Paragraph IV challenges, as some *amici* suggest. *See, e.g.*, Br. of Apotex, Inc. as *Amicus Curiae* Supporting Pet'r at p. 7. The amendments to

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Understanding Patents, FDA and Pharmaceutical Life-Cycle Management (2005).

the Hatch-Waxman Act in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 ("MMA"), contain incentives for multiple Paragraph IV challenges by allowing the first-filer exclusivity period to be shared, and providing methods by which subsequent generic challengers may enter the market despite the terms of any settlement between the patent holder and the first-filer. *See e.g., Dey Pharma, LP v. Sunovion Pharms., Inc.*, 677 F.3d 1158, 1160 (Fed. Cir. 2012) (describing use of declaratory judgment by a subsequent filer to accelerate its ability to market a generic pharmaceutical); Greene, *A Prescription for Change*, 30 J. Corp. L. at 349-50. These amendments incentivize multiple and subsequent generics to pursue Paragraph IV patent challenges.

In addition, the profits available to generic challengers who gain the ability to enter the market can be substantial even without the benefit of the 180-day exclusivity period. Contrary to what some *amici* suggest, evidence shows that it is common to have multiple Paragraph IV challenges after the first challenge has been filed. An economic study found that the average number of generic manufacturers filing a Paragraph IV certification within six months of the first filing increased from approximately 1.5 to nearly two in recent years. Ernst R. Berndt, et al., *Do Authorized Generic Drugs Deter Paragraph IV Certifications? Recent Evidence*, (Working Paper at 12–13, Apr. 2007), http://www.analysisgroup.com/uploadedFiles/Publishing/Articles/PhRMA_Authorized_Generic_Entry.pdf. The same study shows that, not surprisingly, high revenue brand drugs are the most likely targets for Paragraph IV certifications from multiple generic manufacturers. *Id.* at 15.

Indeed, it is not uncommon to find six or more generic challengers in Hatch-Waxman patent cases, with new challengers surfacing throughout the litigation.[9] There is no evidence that the use of reverse payments has diminished the average number of generic manufacturers filing Paragraph IV challenges per drug.

Underlying the argument that reverse payment settlements should be presumptively illegal is the

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[9] *See, e.g., Eli Lilly & Co. v. Wockhardt Ltd.*, No. 08-cv-1547 (S.D. Ind.) (docket sheet for Hatch-Waxman litigation involving nine ANDAs for Cymbalta); *Pfizer, Inc. v. Teva Pharms. U.S.A., Inc.*, 882 F. Supp. 2d 643 (D. Del. 2012) (describing eight lawsuits arising from ANDAs for Lyrica); *Avanir Pharm. Inc. v. Actavis South Atl. LLC*, No. 11-cv-704 (D. Del.) (docket sheet for Hatch-Waxman litigation involving five ANDAs for Nuedexta); Bristol-Myers Squibb Co., Annual Report (Form 10-K), at 101 (Feb. 17, 2012) (describing Hatch-Waxman litigation against seven generic companies regarding Abilify); *SmithKline Beecham Corp. v. Geneva Pharm., Inc.*, 2001 WL 1249694, at *2-4 (E.D. Pa. Sept. 26, 2001) (describing Hatch-Waxman litigation against six groups of generic companies regarding Paxil); *In re Gabapentin Patent Litig.*, 214 F.R.D. 178, 180 (D.N.J. 2003) (noting that Warner Lambert "sued seven generic companies" for filing ANDAs for gapabentin (Neurontin)); *In re Rosuvastatin Calcium Patent Litig.*, 2008 WL 5046424, at *1–3, *7 (D. Del. Nov. 24, 2008) (describing eight ANDAs for Crestor); Sanofi, Annual Report (Form 20-F), at 188 (Mar. 6, 2012) (reporting that generic companies filed "over a dozen ANDA certifications" regarding Eloxatin and that "[e]ach of the generic manufacturers was sued for infringement"); *AbbVie Inc. v. Watson Labs. Inc.*, No. 12-cv-324 (D. Del.) (docket sheet for Hatch-Waxman litigation involving five ANDAs for Niaspan); *Pfizer Inc. v. Apotex Inc.*, No. 12-cv-808 (D. Del.) (docket sheet for Hatch-Waxman litigation involving more than ten ANDAs for Pristiq); Shire plc, Annual Report (Form 10-K), at F-40 (Feb. 23, 2012) (describing six ANDAs for Vyvanse); Abbott Labs., Annual Report (Form 10-K), at 16 (Feb. 23, 2007) (describing six lawsuits arising from ANDAs for Depakote).

mistaken premise that they systematically extend the market exclusivity of brand-name drugs. To the contrary, the average effective length of market exclusivity of brand-name pharmaceuticals has remained constant, if not decreased. *See* Grabowski & Kyle, *Generic Competition and Market Exclusivity Periods*, 28 Managerial & Decision Econ. at 491, 495-96, 501; C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents*, 8 J. Empirical Legal Stud. 613, 640–44. The average length of market exclusivity for drugs experiencing first generic entry in 1995 to 1996 was 13.5 years. During this time period, reverse payment settlements were much less common.[10] For drugs experiencing first generic entry in 2007–2008, the period was reduced by just over one year. *See* Henry G. Grabowski, et al., *Evolving Brand-Name and Generic Drug Competition May Warrant a Revision of the Hatch-Waxman Act*, 30 Health Affairs 2157, 2157–2166 (2011). Thus, the prevailing equilibrium established by Congress has not been disturbed in recent years. *See* Hemphill & Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. Health Econ. at 327–339.

Similarly, if use of reverse payment settlements guaranteed extended exclusivity, one would expect widespread adoption of such settlements. Yet, reverse payments are still only modestly used as a component of patent settlements. With the increase

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[10] According to an FTC study of branded drugs receiving a Paragraph IV challenge between January 1, 1992 and January 1, 2001, only 9 final settlements contained agreements for the brand-name company to pay the generic applicant. *See* FTC, *Generic Drug Entry Prior to Patent Expiration* (July 2002) at 10, 25.

in patent challenges there has been an accompanying increase in the number of settlements. According to Petitioner, settlements have increased tenfold, from 14 in federal fiscal year ("FY") 2004 to 140 in FY 2012. Yet, according to Petitioner only 26 percent of final settlements have included a potential reverse payment since 2004, and this percentage has not increased over time. FTC, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2012 A Report by the Bureau of Competition*, [*Agreements Filed with the FTC* (2012)], http://www.ftc.gov/os/2013/01/130117mmareport.pdf. Moreover, as explained in more detail below, even this figure markedly overstates the number of settlements that include a net payment from a brand to a generic. *See infra* at § D.1.

Nor have settlements with a reverse payment component typically sought to extract all possible profits associated with market exclusivity by delaying entry for the full remaining length of the patent. Instead, settlements—including those Petitioner characterizes as containing reverse payments—typically result in a negotiated patent split that often shortens the effective life of the patent by multiple years, as observed in the current case.

In sum, the available economic evidence does not show that the use of reverse payment settlements has undermined the balance between incentivizing innovation and accelerating the entry of lower-priced generics. The adoption of a standard that threatens to degrade the value of patents in the pharmaceutical industry, thereby diluting the incentive for

investment in innovation, should occur only in the face of strong economic evidence of a clear need to protect consumers. Here, instead, there is clearly dangerous potential for such a standard to, itself, significantly harm consumers. Put differently,

> An antitrust policy that reduced prices by 5 percent today at the expense of reducing by 1 percent the annual rate at which innovation lowers the costs of production would be a calamity. In the long run a continuous rate of change, compounded, swamps static losses.

Frank H. Easterbrook, *Ignorance and Antitrust, in Antitrust, Innovation and Competitiveness* 119, 122-23 (Thomas M. Jorde & David J. Teece eds., 1992).

C. Settlements with Reverse Payments Occur for Reasons Other than Delay and Are Not Presumptively Anticompetitive

Reverse payments in patent settlements can occur for a variety of reasons having nothing to do with payment for delaying entry and therefore should not be treated as presumptively anticompetitive. Real-world complexities such as asymmetric information, differing beliefs regarding the likelihood of prevailing in litigation, differing discount rates, and risk aversion could all lead the parties to negotiate patent settlements that involve reverse payments.

Many of the above complexities result in situations where the parties would be unable to reach a settlement agreement without a reverse payment.[11] For example, efforts to arrive at an

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[11] Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements That Settle Patent Litigation*, Antitrust Bull., 655–698 (Fall 2004); Dickey, et al., *An Economic*

agreement on splitting the remaining patent term may require a generic company to consider entry in the distant future. Indeed, with patent challenges coming earlier in the life of branded drugs, the patent terms at issue can often run more than a decade. Hemphill & Sampat, *When Do Generics Challenge Drug Patents*, 8 J. Empirical Legal. Stud. at 626. A generic company with a high discount rate or uncertainty regarding the future size of the market may be unable to accept a split of the patent term that involves a lengthy wait for the generic to enter as compared to "rolling the dice" on the outcome of litigation. In other words, the generic company may only be willing to accept an entry date that is unacceptable to the brand company, given the brand company's expectations of the likelihood of prevailing in litigation. The parties can use a reverse payment in this situation to bridge the gap and arrive at a settlement where otherwise no settlement would be reached.

Reverse payments can also be used to offset bargaining disadvantages that arise from differences in risk aversion. To avoid a potential loss, a risk averse party is willing to accept unfavorable settlement terms. Brand companies are likely to be more risk averse than their generic challengers because they usually have significantly more to lose from a negative trial outcome. In particular, only a limited number of drugs (sometimes only one)

Assessment of Patent Settlements in the Pharmaceutical Industry, 19 Annals Health L. at 368–400; Gregory K. Leonard & Rika Onishi Mortimer, *Antitrust Implications of Pharmaceutical Patent Litigation Settlements, in Economic Approaches to Intellectual Property Policy, Litigation and Management* 251, 261–264 (NERA Econ. Consulting 2005).

account for the bulk of a brand company's revenue. In contrast, generic companies face virtually no risk other than legal costs. They do not risk damages and tend to be highly diversified such that losing any single patent dispute is unlikely to have significant financial consequences.

Petitioner's efforts to rely on the size of a reverse payment to suggest that the payment has an anticompetitive effect are also misplaced because its approach ignores the role of asymmetric risk aversion. Risk aversion is difficult to measure and to convert into a dollar equivalent. Yet, the relevant costs of litigation are not just the pecuniary outlays and the costs of business disruption, but also include the significant costs of the resulting uncertainty to risk averse parties. For this reason, it is difficult, if not impossible, to determine whether the size of the reverse payment is consistent with the presence of risk aversion amidst the other costs of litigation, and consequently whether the negotiated entry date is consistent with the brand company's assessment of the probability of success, even assuming such assessment were possible. As a result, the size of a reverse payment generally does not provide a reliable benchmark to determine whether the payment is anticompetitive.

Because there are many reasons why reverse payment settlements maintain the balance between static and dynamic efficiencies, and enable pro-competitive settlements, such settlements should not be considered presumptively illegal.

D. Petitioner's Data Are Insufficient to Justify Adopting a Presumptive Illegality Standard.

Petitioner acknowledges that there are two possible outcomes if reverse payments are not allowed: (1) Parties reach settlement without reverse payments; or (2) Parties are unable to settle and litigate instead. Petitioner bases its argument for the presumptive illegality standard and its critique of the scope of the patent test on the claim that consumers, on average, would be better off under either outcome. However, Petitioner uses flawed reasoning and unreliable evidence to support its claim.

1. Petitioner's Overly Broad Definition of Reverse Payment Settlements Taints Its Economic Analysis.

Any analysis of the economic consequences of reverse payment settlements requires a reasonable *definition of "reverse payments" as a starting point.* Yet *all of* Petitioner's economic analysis turns on an overly broad definition of what constitutes a "reverse payment" settlement.

Essentially, Petitioner treats any form of consideration from the patent holder to a generic challenger as a "reverse payment." For example, a brand company's agreement in a patent settlement not to introduce a generic version of its brand drug to compete against its licensee's generic (while continuing to sell its branded drug) would, in Petitioner's view, qualify as a "reverse payment." Last year, agreements of this kind accounted for almost half of the supposed "reverse payment"

settlements. *Agreements Filed with the FTC* (2012) at 1, http://www.ftc.gov/os/2013/01/130117mmareport.pdf. Yet, this is just a watered-down version of an exclusive licensing arrangement frequently found in license agreements. Petitioner's statistics provide no information about whether the generic paid a royalty to obtain such an exclusive license. If settlements where an agreement not to introduce an authorized generic is the only form of "reverse payment" are excluded, then between 2010 and 2012 only about 13 percent of settlements included a potential reverse payment. *Id.* at 2.

In addition, even settlements that include a financial transfer from a brand to a generic may not truly be "reverse payment" settlements. For example, a settlement of a patent dispute between a brand and a generic that involves some form of a patent split and a contemporaneous business transaction is characterized by Petitioner as a "reverse payment" settlement. [12] The magnitude of the brand company's payment to the generic company in such transactions would have to be evaluated against the value the generic conferred on the brand to determine whether there has been a true "reverse payment."

There is typically significant ambiguity around the value of such agreements because they often include the purchase of intellectual property, real options (through joint ventures), supply agreements,

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[12] *Agreements Filed with the FTC* (2009) at p. 2, http://www.ftc.gov/reports/mmact/MMAreport2009.pdf (noting that almost half of potential reverse payment settlements filed in 2009 involved side deals in which the compensation did not relate directly to the elements of the patent dispute).

risk sharing, and the settlement of other litigation. Determining the value of such one-of-a-kind business agreements can be very difficult. *See Protecting Consumer Access to Generic Drugs Act of 2009: Hearing on H.R. 1706 Before House Subcomm. on Commerce, Trade and Consumer Prot.*, 111th Cong. 25 (Mar. 31, 2009) (prepared statement of C. Scott Hemphill, Assoc. Prof. of Law, Columbia Univ., at 47) ("In some cases, the generic firm has plausible expertise in the subject of the side deal. It can be difficult to be certain that a deal is collusive without a deep and complex inquiry into the business judgment of the two drug makers."). This underscores the weakness of Petitioner's argument that the parties to such a transaction will be able to deconstruct a complicated business arrangement to rebut a presumption of illegality.

Further, even Petitioner concedes that payments that are commensurate with the patent holder's expected litigation costs do not indicate an unreasonable delay in generic entry and should not be treated as illegal. Pet'r Br. at 38. However, Petitioner's calculation of the number of reverse payment settlements apparently includes settlements with net payments lower than the brand firm's expected litigation costs. *See, e.g., Agreements Filed with the FTC* (2006) at p. 3, http://www.ftc.gov/reports/mmact/MMAreport2006.pdf. Moreover, as explained above, the true costs of litigation include the hard-to-measure costs of the resulting business uncertainty to the risk averse parties, in addition to the outlays for legal fees.

In total, between fiscal years 2004 and 2009, 88 percent of the settlements Petitioner characterized as "reverse payment" settlements were categorized as

such because of contemporaneous business transactions (44 percent), agreements not to launch brand-authorized generics (38 percent), or both (three percent), or a payment that was less than tangible saved litigation expenses (three percent). *See Agreements Filed with the FTC* (2004–2009). If these settlements had not been categorized as reverse payment settlements, only four percent of all settlements over this six year period, eight settlements in total, would have been categorized as reverse payment settlements.

Petitioner's difficulty in establishing a rational definition of reverse payment settlements may stem from the fact that there is no economically sound basis to distinguish these settlements from other patent settlements. Through the Hatch-Waxman Act, Congress has created a form of theoretical infringement on the part of the generic firm without actual entry into the market, and thus without any potential damage exposure on the part of the alleged infringer. This feature of the Hatch-Waxman Act encourages generic challenges but also implies that compensation flowing from the patent holder to the infringer cannot take the form of forgiveness of damages. In contrast, in patent cases where entry has occurred, a settlement by the patent holder often includes reducing all or a portion of its damages claims against the alleged infringer. That is a form of compensation flowing from the patent holder to the alleged infringer and is no different in an economic sense from reverse payments seen in pharmaceutical patent settlements. *See* Marc G. Schildkraut, *Patent-Splitting Settlements and Reverse Payment Fallacy*, 71 Antitrust L.J. 1033, 1048, 1055-56, 1067 (2003-04). For example, suppose

an incumbent company alleges that its patent was infringed when another company entered the market and claims lost profits of one million dollars. Because the incumbent may not be fully confident that its patent will be found valid and infringed, it may settle by agreeing that if the infringer exits the market for some or all of the remaining life of the patent, it will forgo some or all compensation for its lost profits. In such scenarios, the incumbent is forgoing payment from the infringer, which is economically no different from actually paying the infringer. Indeed, a ruling that reverse payment settlements are presumptively unlawful could result in patent settlements outside of the pharmaceutical industry being subjected to antitrust scrutiny. Such a ruling would thus have far-reaching effects on the ability of litigants to settle patent litigation.

Petitioner's overly broad definition renders its economic analysis of the prevalence and impact of "reverse payment" settlements meaningless. The difficulty in identifying "reverse payment" settlements also highlights an additional problem with Petitioner's approach. Because identifying "reverse payment" settlements requires a complex analysis of contemporaneous business transactions, litigation costs, and risk aversion, the presumptive illegality standard would be difficult to apply and would create substantial uncertainty for parties attempting to settle patent disputes.

2. Petitioner's Calculation of Generic Litigation Victories Is Not a Meaningful Figure

Petitioner also relies on the calculation that, as of June 2002, generic companies had won 73 percent of patent cases that were fully litigated. *See* Pet'r Br.

at 6 (citing FTC, *Generic Drug Entry Prior to Patent Expiration* (July 2002) at 19–20). However, this statistic provides no information about the expected outcome of any specific patent dispute or the proportion of patents in dispute today that would be found invalid or infringed were they to be fully litigated.

The percentage Petitioner relies on cannot serve that purpose for two primary reasons. First, the statistic is based on early patent challenges (fully litigated by June 2002). Early patent challenges focused on products with narrower patents, which likely contributed to the high success rate for generic companies when patents were fully litigated during that period. *See* Hemphill & Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. Health Econ. at 327–28 (describing trends in patent challenges). But that success rate applies only to the pre-2002 period and not to the more recent period when almost every patent is challenged, particularly for drugs with large sales. A more recent study of pharmaceutical patent litigation by RBC Capital Markets analyzed 370 final court decisions during the period from 2000 to 2009 and found that brand firms prevailed in 52 percent of the cases that went to trial. Adam Greene & D. Dewey Steadman, *Pharmaceuticals: Analyzing Litigation Success Rates*, RBC Capital Markets, at 1 (Jan. 15, 2010), http://www.aipla.org/committees/committee_pages/FDA/Committee%20Documents/Meeting%20Materials/2010%20Spring%20Meeting/AnalyzingLitigationSuccessRates.pdf.[13] Any

[13] See also Laura E. Panattoni, *The Effect of Paragraph IV Decisions and Generic Entry before Patent Expiration on Brand Pharmaceutical Firms*, 30 J. Health Econ. 126, 127, 137 (2011)

reliance on studies of outcomes of patent litigation must also account for the high rates of reversal in patent litigation, which Petitioner does not do. *See* Stephen P. Swinton & Adam A. Welland, *Patent Injunction Reform and the Overlooked Problem of 'False Positives'*, 70 Pat., Trademark & Copyright J. 337 (July 2005) (noting the "disturbing" rate of reversals after patent trials).

Second, this statistic provides no information about any net benefit to consumers since an unsuccessful challenge to patents providing ten years of market exclusivity and billions of dollars in sales has a far greater impact on short-term consumer welfare than successful challenges to patents with five years of exclusivity for drugs with relatively modest sales.

3. Petitioner's Calculation of the Costs Associated with Reverse Payment Settlements Is Not a Reliable Measure of Harm to Consumers

Petitioner and other *amici* rely heavily on Petitioner's calculation that, on average, patent settlements with potential reverse payments have an exclusion period 17 months longer than patent settlements without reverse payments, and that reverse payment settlements therefore cost consumers $3.5 billion annually.[11] FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers*

(showing that brand companies won 34 out of 72 challenges between 1988 and 2007, and 24 out of 41 challenges between 2003 and 2007, the last five years of the sample).

[11] *See, e.g.*, Br. for the State of New York *et al.* as *Amici Curiae* at p. 3; Pet'r Br. at 31; Br. for AARP, *et al.*, as *Amici Curiae* at 4–5, 10.

Billions at p. 4 (2010), http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf. The data Petitioner cites are of questionable validity and the conclusions Petitioner draws from them are unsupported by solid economic evidence.

Petitioner defines the exclusion period as the time between settlement execution and the agreed-upon generic entry date. Petitioner calculates that the sales-weighted exclusion period for settlements with reverse payments is 17 months longer, on average, than for settlements without reverse payments, and claims that this implies that reverse payments cause generic entry to be later than it otherwise would be. FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (2010). In turn, Petitioner's cost estimate is based on multiplying (1) the supposed period of delay by (2) Petitioner's estimate of the reduction in price that exists in a mature generic market by (3) the volume of sales it estimates reverse payment settlements impact each year. Petitioner's inference that patent litigation would result in earlier generic entry but for reverse payment settlements, and that these settlements therefore impose high costs on consumers, is incorrect for a number of reasons.

As an initial matter, the data underlying Petitioner's calculation are not available to anyone other than Petitioner. As a result, it is impossible to audit Petitioner's calculations or to correct the flaws in Petitioner's methodology. In addition, as we explained above, *see* § D.1, an important flaw in Petitioner's estimate of the supposed period of delay is its use of an overly broad definition of potential reverse payments to categorize settlements. We are not aware of any analysis concerning differences in

the exclusion periods that employs a more reasonable definition of settlements with net payments from a brand to a generic challenger. Petitioner's overly broad definition of reverse payments also greatly inflates Petitioner's estimate of the volume of sales affected by reverse payment settlements.

Moreover, even if Petitioner's categorization of settlements were correct, correlation does not prove causation. There may be other reasons why settlements with reverse payments have longer exclusion periods that have nothing to do with payment for delay. For example, reverse payment settlements may differ from other settlements in terms of average patent life remaining, or the point in the drug's life cycle when settlement is reached. *See* Bret Dickey, Jonathan Orszag & Robert Willig, *A Preliminary Economic Analysis of the Budgetary Effects of Proposed Restrictions on "Reverse Payment" Settlements* at p. 3 (Aug. 10, 2010), http://www.compasslexecon.com/highlights/Documents/Dickey%20Orszag%20Willig%20CBO.pdf. To our knowledge, Petitioner has reported no analysis to rule out alternative explanations. In particular, Petitioner apparently has done no analysis to show that the patent lengths at issue in settlements with and without a reverse payment are comparable.

Other concerns with the study have been raised as well. For instance, the 17-month figure is likely to be overstated because it assumes that the generic company was capable of entering the market by the entry date the parties supposedly would have negotiated absent a reverse payment, which is not necessarily the case. *See* Kyle Musgrove & Richard Ripley, *Reverse Payment Settlements: Presumptively*

Bad or Usually Acceptable. CPI Antitrust Chron. (June 2012 (2)). The appropriate measure would take into account when the generic company could have gone to market, an analysis that requires a determination both of when FDA would have given final approval and the entry date that the parties would have negotiated absent a reverse payment.

The reduction in price is also likely to be overstated because Petitioner does not take into account price discounts such as rebates and free samples that brand companies provide and generic companies generally do not.[15]

Lastly, Petitioner's study provides no reason to believe that a reverse payment settlement would otherwise be a settlement without a reverse payment. Absent use of a reverse payment the parties may not reach settlement at all, and the litigation may continue to trial.[16] *See supra* C. However, Petitioner's study does not consider how generic entry dates under reverse payment

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[15] *See* Henry Grabowski, Tracy Lewis, Rahul Guha, Zoya Ivanova, Maria Salgado & Sally Woodhouse, *Does Generic Entry Always Increase Consumer Welfare?*, 36th Ann. Proc. Fordham Competition L. Inst., Ch. 12 (2010); Dep't Health & Human Servs., Office of the Inspector General, *Concerns with Rebates in the Medicare Part D Program* (March 2011).

[16] Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, Antitrust Bull., 655–698 (Fall 2004); Dickey, et al., *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 Annals Health L., at 368–400; Gregory K. Leonard & Rika Onishi Mortimer, *Antitrust Implications of Pharmaceutical Patent Litigation Settlements, in Economic Approaches to Intellectual Property Policy, Litigation and Management* 251, 261–264 (NERA Econ. Consulting 2005).

settlements would compare to generic entry dates under litigation. Petitioner's study also fails to account for the costs associated with increased litigation.

Petitioner assumes that the entry dates agreed to in settlements without reverse payments reflect the likely outcome of litigation and therefore provide a "benchmark for the consumer impact of either alternative."[17] This assumption is unfounded. For a variety of reasons, including risk aversion and the parties having only a vague sense of their likelihood of prevailing in litigation, settlement agreements without reverse payments may not reflect what would occur, on average, were the patent cases to be fully litigated.

Indeed, determining whether a settlement reflects the likely outcome of litigation is, in general, a challenging task. Doing so would require a means of assessing the merits of the underlying patent case from which one could calculate the expected generic entry date based on the probability that the patent would be found valid and infringed if it were fully litigated. For example, if the patent holder has a probability of prevailing in litigation of 75 percent and a probability of failing of 25 percent, then any agreement that leaves the patent holder with more than 75 percent of its remaining patent life would be considered anticompetitive under this standard, whether or not it includes a reverse payment.

The problems with this approach in the real world are both substantial and obvious. Not all the

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[17] FTC, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions at p. 9 (2010).

information relevant to the litigation and trial is available at the time of settlement. thus there is inherent uncertainty regarding the outcome of the trial. Even if all the information were available, it would still not be straightforward to assign probabilities to the possible litigation outcomes. Patent litigation is notoriously unpredictable. with high rates of reversal. These reversals include both false positives (*i.e.*, incorrectly finding patents valid and infringed) and false negatives (*i.e.*, incorrectly finding patents invalid or not infringed) at rates so high that some commentators have referred to it as "disturbing." Stephen P. Swinton & Adam A. Welland, *Patent Injunction Reform and the Overlooked Problem of 'False Positives'*, 70 Pat., Trademark & Copyright J. 337 (July 2005).

Moreover, brand companies must assess more than just the ultimate resolution of a case. Prevailing in the Federal Circuit on appeal does little for a brand company that loses in the district court and is unable to stave off generic entry. In the interim, the brand loses its market exclusivity, and experiences a rapid erosion of market share and a decline in price.

Determining the probability that the brand company will win a patent case is, of course, different from, and much harder than, actually trying the patent case to verdict. Trying the patent case once yields a discrete outcome, which itself could be influenced by specific factors such as the particular fact finder and the effectiveness of counsel, the experts, and other witnesses. The discrete outcome from this litigation would not provide a reliable estimate of the *ex-ante* probability that the patent

would be found valid and infringed.[18] To obtain such an estimate would require the impracticable, trying the case a large number of times. Of course, litigating the patent case is precisely what the parties seek to avoid by settling in the first place.

Thus neither past settlements nor past litigation outcomes can be used to assess reliably when entry is likely to occur under litigation. All that is known is that, through litigation, the generic would win some fraction of cases, with entry generally occurring at the end of a potentially lengthy litigation process, and the brand would win the remainder, with entry delayed until patent expiration. Without knowing which cases would fall into each category, it is problematic to determine whether litigation, on average, benefits consumers. Reaching such an understanding would require assessing the patent holder's likelihood of success in the infringement suit, a task Petitioner states is "inappropriate and cumbersome." Pet'r Br. at 54–55.

Further, to the extent that reverse payments are necessary to achieve settlement, Petitioner's estimate of the costs associated with reverse payment settlements must be offset by the impact of increased litigation. Less litigation through settlements eases the burden on the court system, and can provide economic efficiencies by reducing

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[18] Courts that have rejected Petitioner's presumptive illegality rule have recognized this concern. *See, e.g., Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1308 (11th Cir. 2003) ("Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent.").

costs associated with court delay and hasty considerations when cases reach trial.[19] Settlement is also generally less expensive since litigants avoid fees for lawyers and experts, costs associated with the time and effort of firm employees and managers, both of which may be passed on to consumers in the form of higher prices, and the costs to risk averse parties of bearing substantial business uncertainties. *See, e.g.*, Bret Dickey, Jonathan Orszag & Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 Annals Health L. 368, 375–76 (2010).

Petitioner has thus done nothing to show that eliminating reverse payments would result in lower average costs to consumers. It is just as plausible that increased litigation would lead to average outcomes that increase costs to consumers.[20] Petitioner has thus come forward with inadequate economic evidence to justify adopting a new standard that would presumptively bar reverse payment settlements.

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[19] *See, e.g.*, William M. Landes, *An Economic Analysis of the Courts*, 14 J.L. & Econ. 61, 74 (Apr. 1971) ("It is widely recognized that the courts are burdened with a larger volume of cases than they can efficiently handle. The results are often long delays prior to trial, and hasty consideration when cases reach trial." citing U.S. Pres. Comm'n on Law Enforcement and Admin. of Justice, Task Force on the Admin. of Justice, Task Force Report: The Courts, at 38–40 (1967)).

[20] Petitioner's calculation also fails to consider any corresponding impact on innovation, if the Court were to adopt a standard that undermined the value of patents in encouraging pharmaceutical research and development.

CONCLUSION

The available economic evidence does not support Petitioner's effort to impose a standard of presumptive illegality on certain forms of patent settlements. At present:

- Most patented drugs are challenged.
- Most settlements assure generic entry before patent expiration.
- Generics account for a huge and increasing percentage of prescription drug volumes.
- Market exclusivity periods have not increased.

For these reasons, the standard Petitioner advances should not be adopted by this Court.

Respectfully submitted.

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APPENDIX

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AMICUS CURIAE BRIEF

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Supreme Court of the United States

FEDERAL TRADE COMMISSION,

Petitioner,

v.

WATSON PHARMACEUTICALS, INC., ET AL.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF OF APOTEX, INC. AS *AMICUS CURIAE* SUPPORTING PETITIONER

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INTEREST OF *AMICUS CURIAE*

Apotex, Inc. is a leading generic pharmaceutical manufacturer with customers in the United States, as well as 115 other countries, and annual sales in excess of $1 billion. As a major market participant, Apotex has a significant interest in the proper application of federal competition law to the American pharmaceutical market. This market features unique barriers to entry regulated, in part, by the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585—a law directed at the intersection of the patent laws and the federal Food, Drug and Cosmetic Act (FDCA). In addition, Apotex is a party to patent litigation that includes antitrust claims against Cephalon, Inc., the brand manufacturer of the drug modafinil. *See Apotex, Inc.* v. *Cephalon, Inc.*, No. 2:06-cv-2768 (E.D. Pa.) (antitrust claims stayed), *patent appeal filed*, No. 12-1417 (Fed. Cir.). The resolution of the present case could have a profound effect on the relative merits of Apotex's claims in that litigation. As a result, Apotex's interests in this case are substantial.[1]

Apotex also is unique among generic manufacturers in arguing that the courts should apply heightened antitrust scrutiny to settlements between

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[1] Counsel for all parties have consented to the filing of this brief, and those consents are on file with the Clerk of the Court. No counsel for a party in this case authored this brief in whole or in part. No person or entity—other than Apotex or its counsel—made a monetary contribution specifically for the preparation or submission of this brief.

brand-name and generic drug manufacturers that include any form of reverse payment. For this reason, Apotex does not support the position that its trade association has taken in cases like this one, because that organization has advocated for a test that would essentially insulate these types of settlement agreements from antitrust scrutiny—the so-called "scope-of-the-patent" test. *See* Br. for Generic Pharm. Ass'n as *Amicus Curiae* at 21-22, *Upsher-Smith Labs., Inc.* v. *Louisiana Wholesale Drug Co.*, No. 12-265 (U.S.) (filed Oct 1, 2012). In addition, Apotex's Chief Executive Officer, Dr. Bernard Sherman, has testified before Congress about the current ability of brand-name and generic drug manufacturers to structure their settlement agreements in a way that effectively blocks other generic manufacturers from challenging weak drug patents. *See The Protecting Consumer Access to Generic Drugs Act of 2009: Hearing on H.R. 1706 Before the Subcomm. on Commerce, Trade and Consumer Protection of the H. Comm. on Energy and Commerce*, 111th Cong. 214-29 (2009) (statement of Bernard Sherman, CEO, Apotex, Inc.). Accordingly, Apotex has repeatedly demonstrated its commitment to a fair playing field—one that reasonably rewards and protects innovation, while ensuring that erroneously-issued patents are not exploited to the detriment of American consumers.

Apotex submits this brief as an *amicus curiae* to draw the Court's attention to several errors in a critical assumption underlying the scope-of-the-patent test. The courts that have adopted this test (including the one below) have candidly acknowledged that it would insulate reverse-payment settlements from

any form of meaningful antitrust scrutiny, allowing brand-name drug manufacturers to share monopoly profits with their generic rivals even in situations where the underlying patent has no "*actual* exclusionary power." *E.g.*, *FTC* v. *Watson Pharms., Inc.*, 677 F.3d 1298, 1308, 1315 (11th Cir. 2012). But these courts have reasoned that, "[i]f the patent actually is vulnerable, then presumably other generic companies . . . will attempt to enter the market and make their own challenges to the patent." *Id.* at 1315. A proper understanding of the pharmaceutical market—including the unique legal setting in which it operates—reveals the errors in this critical assumption.

SUMMARY OF THE ARGUMENT

In this case, the parties have focused on the potential anticompetitive nature of patent-infringement settlements among brand-name and generic drug manufacturers that include a reverse payment—and rightly so. Such a payment allows a brand-name drug manufacturer to share monopoly profits with a generic rival, in the hope of staving off generic competition, even where the underlying patent would not survive judicial scrutiny. In these circumstances, the settlement agreement operates as a naked restraint of trade—an agreement not to compete—and it should be subject to heightened antitrust scrutiny under a "quick look" rule-of-reason approach.

A number of courts (including the one below) have rejected this straightforward approach and, instead, have insulated virtually all reverse-payment settlements from any form of meaningful antitrust scruti-

ny—even in situations where the underlying patent would not survive judicial review. The courts that have adopted this approach have acknowledged as much. *See, e.g.*, *Watson Pharms.*, 686 F.3d at 1315.

These courts, however, have discounted the concern that such a test would allow weak drug patents to go completely untested, based on the assumption that non-settling generic manufacturers are equally motivated to come forward to challenge the patent at issue. For instance, the court below reasoned that "there usually are many potential challengers to a patent, at least to drug patents," and that, "[i]f the patent actually is vulnerable, then presumably other generic companies . . . will attempt to enter the market and make their own challenges to the patent." *Id.*

This foundational assumption is based on an erroneous understanding of the pharmaceutical market. That market does not provide non-settling generic manufacturers with the same incentives as the initial generic challenger.

To begin with, "the initial generic challenger is necessarily the most motivated because, unlike all subsequent challengers, it stands to benefit from the 180-day exclusivity period of 21 U.S.C. § 355(j)(5)(B)(iv)." *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 215 (3d Cir. 2012), *petitions for cert. pending*, No. 12-245 (filed Aug. 24, 2012) and No. 12-265 (filed Aug. 29, 2012). In passing the Hatch-Waxman Act, Congress recognized that, following complete generic market entry, the profit margins are not necessarily sufficient to encourage any single generic manufacturer to undertake the risk of launching a

lengthy and costly legal challenge against a brand manufacturer's patent. As a result, Congress provided a 180-day period of generic market exclusivity as a reward to encourage at least one generic manufacturer to undertake such a challenge. This period of generic exclusivity is triggered on the day that the first filer begins to commercially market its drug. *See id.* "Notably," however, "the 180-day exclusivity window is only available to the first filer," which means that "even if the first filer never becomes eligible to use its 180-day exclusivity period because it settles, loses, or withdraws [from] litigation, that potential benefit will not pass to subsequent filers." *K-Dur*, 686 F.3d at 204. Stated simply, subsequent generic challengers are not eligible to avail themselves of the carrot afforded to their first-filing brethren.

It might be one thing if non-settling generics were merely deprived the exclusive carrot established by the Hatch-Waxman Act, but they also face a stick, a so-called poison-pill clause, wielded by their settling rivals to affirmatively beat back challenges to weak drug patents. The typical poison-pill clause—including the one at issue in this case—provides that the settling generic manufacturer agrees not to market a generic version of the patented drug until a specific date, but it may immediately market such a version, and still reap the benefit of its 180-day period of generic market exclusivity, if another generic company is successful in challenging the drug's patent. *See* Compl. ¶¶ 65, 76, J.A. 46, 49; *see also* Br. for Pet. at 52 (describing the operation of these clauses and noting that their inclusion is "typical" in Hatch-Waxman settlements). As a result, a poison-pill clause renders it economically irrational for non-

settling generic manufacturers to continue their challenges to the patent at issue, because the clause ensures that, even if they are successful in challenging the patent, they will be deprived of the benefit of their labors and forced to enter the market 180 days after the settling first filer has entered.

The combination of no carrot and an affirmative stick helps to explain why non-settling generic manufacturers have not stepped forward to challenge weak drug patents covered by a settlement agreement between a brand-name manufacturer and an initial challenger. The carrot itself is a thing of immense value. By some estimates, an eligible generic manufacturer stands to gain several hundred million dollars during its 180-day period of generic market exclusivity. *See* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1560 (2006). Because subsequent challengers are not eligible to receive this valuable reward, they lack the same incentive to challenge the patent at issue. What is more, a non-settling generic manufacturer faces a stick as well: the immense cost of litigating a patent challenge—"$10 million or more," *see* C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 Antitrust L.J. 947, 952 (2011)—coupled with the certainty that the subsequent challenger will not reap the rewards of its labors.

The fact that non-settling generic manufacturers are outright discouraged from maintaining their own challenges to a drug patent further demonstrates why this Court should apply quick-look scrutiny to

any form of reverse-payment settlement between brand-name and generic pharmaceutical manufacturers. The alternative approach—the scope-of-the-patent test—would essentially insulate these highly anticompetitive settlement agreements from judicial review, while allowing the settling parties to structure their agreements in a manner that discourages non-settling parties from maintaining their own challenges to the patent at issue. In short, the scope-of-the-patent test would allow the weakest drug patents to go completely untested—permitting the settling parties to divvy up ill-deserved monopoly profits—at an enormous cost to American consumers.

ARGUMENT

BECAUSE NON-SETTLING GENERIC MANUFACTURERS ARE DISCOURAGED FROM CHALLENGING PATENTS COVERED BY A REVERSE-PAYMENT SETTLEMENT, THE SCOPE-OF-THE-PATENT TEST WOULD EFFECTIVELY INSULATE WEAK DRUG PATENTS FROM ANY FORM OF JUDICIAL SCRUTINY.

A number of courts (including the one below) have held that, "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." *Watson Pharms.*, 677 F.3d at 1312; *accord In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008), *cert. denied*, 129 S. Ct. 2828 (2009); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213-14 (2d Cir. 2005), *cert. denied sub nom.*, *Joblove* v. *Barr Labs, Inc.*, 551 U.S. 1144 (2007). Under this approach, "a

patent's *actual* exclusionary power" is irrelevant. *Watson Pharms.*, 677 F.3d at 1308. Rather, what matters is the patent's "*potential* exclusionary" power, which the Eleventh Circuit describes as "the exclusionary rights appearing on the patent's face and not the underlying merits of the infringement claim," *id.* at 1311 n.8 (emphasis added).

In practice, the scope-of-the-patent test "does not subject reverse payment agreements to any antitrust scrutiny," *K-Dur*, 686 F.3d at 214—even in situations where the underlying patent would not survive judicial review. The courts that have adopted this test have acknowledged as much. For instance, the Eleventh Circuit did not dispute that, under the scope-of-the-patent test, potential drug rivals might be able to "'forgo litigation over patent infringement and split up an ongoing stream of monopoly profits, even in situations in which it is evident that it is more likely than not that the patent would be found invalid or not infringed.'" *Watson Pharms.*, 677 F.3d at 1315. Similarly, the Second Circuit acknowledged the possibility that, through these settlements, colluding pharmaceutical manufacturers could extend an "ill-gotten patent monopoly." *Tamoxifen*, 466 F.3d at 212.

The courts that have adopted the scope-of-the-patent test have discounted this serious concern—that parties might agree to forgo challenges to even weak drug patents and split ill-deserved monopoly profits—based on the assumption that non-settling generic manufacturers are equally motivated to come forward to challenge the patent at issue. The Eleventh Circuit presumed that other potential challeng-

ers have the same incentive to "enter the waters by filing their own paragraph IV certifications attacking the patent." *Watson Pharms.*, 677 F.3d at 1315. Similarly, the Second Circuit believed that "other potential generic manufacturers" would be able to avail themselves of the Hatch-Waxman Act's 180-day period of generic market exclusivity, even after the initial generic challenger had agreed to settle and drop its challenge to the patent at issue. *See Tamoxifen*, 466 F.3d at 214.

The assumption that others will come along to challenge weak drug patents is critical to the operation of the scope-of-the-patent test, because it presumes that the market will limit the reach of otherwise anticompetitive settlements between brand-name and generic pharmaceutical manufacturers. For this reason, the Second Circuit further assumed that the holder of a weak patent could not "'stave off *all* possible challengers with exclusion payments because the economics simply would not justify it.'" *Id.* at 212 (quoting *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 535 (E.D.N.Y. 2005)).

But these underlying assumptions are easily proved false. Non-settling generic manufacturers do not have the same incentives to challenge a patent in the face of a settlement agreement between a brand-name manufacturer and the initial generic challenger. In fact, non-settling generic manufacturers are actively *discouraged* from continuing to maintain their own challenges to the patent at issue. Moreover, in many situations, the underlying economics

would allow brand-name manufacturers to essentially "buy off" all possible challengers.

As a result, even aside from the many legal flaws that undermine the scope-of-the-patent test's deferential treatment of reverse-payment settlements—flaws that are recounted at length by the Federal Trade Commission, *see* Br. for Pet. at 19-51—the scope-of-the-patent does not properly "recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies." *Verizon Commc'ns, Inc.* v. *Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004). This misapprehension of the economic and legal landscape further demonstrates why this Court should reject the scope-of-the-patent test in favor of the "quick look," truncated rule-of-reason analysis adopted by the Third Circuit in *K-Dur*.

A. The Scope-of-the-Patent Test is Premised, in Large Part, on the Erroneous Assumption that Non-Settling Generic Manufacturers Will Come Forward to Challenge Weak Drug Patents.

Because the scope-of-the-patent test would, in practice, shield reverse-payment settlements from any form of antitrust scrutiny, *see K-Dur*, 686 F.3d at 214; *see also Watson Pharms.*, 677 F.3d at 1315 (acknowledging the same), there is a risk that a brand-name manufacturer could stave off challenges by each of its generic rivals even when a patent would not withstand judicial scrutiny—protecting undeserved monopoly profits—at an enormous cost to American consumers. The courts that have adopted the scope-of-the-patent test have assumed that this

risk is mitigated, because other generic manufacturers will come forward to challenge weak drug patents, and because a brand-name manufacturer cannot afford to "buy off" all generic challengers. Both assumptions are unsound.

1. Non-Settling Generic Manufacturers Do Not Have the Same Incentives to Challenge Drug Patents Covered by Settlements Between a Brand-Name Manufacturer and the Initial Generic Challenger.

Non-settling generic manufacturers lack sufficient incentives to challenge a drug patent covered by a settlement between a brand-name manufacturer and the initial generic challenger. For one thing, although the Hatch-Waxman Act included a provision intended to encourage at least one generic manufacturer to challenge a drug patent, that provision has been interpreted such that it is available only to the initial challenger of a drug patent. For another, settling drug manufacturers have included within their agreements a so-called "poison-pill" clause to actively discourage non-settling generic manufacturers from continuing to maintain their own challenges to the patent at issue.

a. Only the initial generic challenger may avail itself of a provision of the Hatch-Waxman Act designed to encourage generic manufacturers to challenge weak drug patents.

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585, "which amended the FDCA

and the patent laws in several important respects." *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 665 (1990). As its formal name implies, the Hatch-Waxman Act "struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to the market." *Andrx Pharms., Inc.* v. *Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002); *accord* H.R. Rep. No. 98-857, pt. 2, at 7 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2691 (discussing this legislation as "the best possible compromise between two competing economic interests").

Within the balance struck by Congress, the Hatch-Waxman Act provides an incentive for generic manufacturers to challenge a drug patent's validity or to invent around its reach: The first generic manufacturer to file a paragraph IV certification (certifying that the patent is invalid or not infringed) is granted a 180-day period during which the FDA will not make effective any other application to market a generic version of that drug. *See* 21 U.S.C. § 505(j)(5)(B)(iv); *K-Dur*, 686 F.3d at 204 (describing the 180-day provision as a form of encouragement); *accord* FDA, *Effective Date of Approval of an Abbreviated New Drug Application*, 63 Fed. Reg. 59,710, 59,711 (Nov. 5, 1998) (stating that the 180-day period was "created as an incentive to generic manufacturers to challenge patents that may be invalid, not infringed, or unenforceable"); *see also* H.R. Rep. No. 98-857, pt. 1, at 28 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2661 (discussing the operation of this period of generic market exclusivity).

Good intentions aside, Congress left the 180-day provision susceptible to an interpretation that grants the reward of exclusivity even to first filers who do not succeed in proving that the patent is invalid or not infringed. Under this interpretation of the 180-day provision, as long as the generic manufacturer does not lose in litigation, it may retain this exclusivity—even if it does nothing else.

The FDA initially resisted this interpretation, insisting that the first-to-file generic had to mount a "successful defense" to a brand manufacturer's infringement action. *See* FDA, *Policy on 180-Day Marketing Exclusivity for Drugs Marketed Under Abbreviated New Drug Applications; Clarification*, 62 Fed. Reg. 63,268, 63,268 (Nov. 28, 1997). But the FDA ultimately abandoned this position after it was invalidated by a handful of courts. *See, e.g.*, *Mova Pharm. Corp.* v. *Shalala*, 955 F. Supp. 128, 130 (D.D.C. 1997) ("The language of the statute . . . is plain and unambiguous. It does not include a 'successful defense' requirement, and indeed it does not even require the institution of patent litigation."), *aff'd*, 140 F.3d 1060 (D.C. Cir. 1998); *see also* Ctr. for Drug Evaluation & Research, FDA, *Guidance for Industry: 180-Day Generic Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act* 4 (1998) (stating that the "FDA will not enforce the 'successful defense' provisions" and would "formally remove" them from the Code of Federal Regulations) (available at: http://www.fda.gov/downloads/Drugs/.../Guidances/ucm079342.pdf) (last viewed Jan. 28, 2013).

Importantly, rather than find a middle ground following the invalidation of its "successful defense" approach, the FDA abandoned altogether any requirement that the first filer do anything beyond being the first to file a paragraph IV certification. *See* 21 C.F.R. § 314.107(c)(1). Moreover, the FDA has maintained this position, even though the Hatch-Waxman Act defines a "first applicant" as one who first "submits a substantially complete application that contains *and lawfully maintains*" a certification that the patent is invalid or otherwise not infringed. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb) (emphasis added); *see also Earning Exclusivity*, 77 Antitrust L.J., *supra*, at 969-71 (arguing that the "first applicant" provision should be interpreted to require the first filer to earn its period of generic exclusivity by maintaining a legal challenge to the patent at issue). As a result, the 180-day exclusivity period is available only to the first generic manufacturer to file a paragraph IV certification, "even if the first filer never becomes eligible to use its 180-day exclusivity period because it settles, loses, or withdraws [from] litigation." *K-Dur*, 686 F.3d at 204 (citing 21 U.S.C. § 355(j)(5)(D)(iii)).

Regardless of the propriety of this interpretation, it has a profound—and, perhaps, underappreciated—effect on settlements between brand and first-to-file generic manufacturers. As an initial matter, it provides the first-to-file generic manufacturer with a unique incentive unmatched by its generic rivals. *See Paying for Delay*, 81 N.Y.U. L. Rev., *supra*, at 1583 (noting "a sharp difference in incentives . . . between [the first paragraph IV] filer and all other generic firms"). Indeed, one scholar estimated that

such exclusivity can be "worth several hundred million dollars to a generic firm that successfully challenges the patents on a major drug." *Id.* at 1579 & n.110 (citing as an example litigation in which Apotex prevailed). Moreover, the Second and Eleventh Circuits have assumed, erroneously, that "other potential generic manufacturers" would be able to avail themselves of this period of generic exclusivity, even after the first filer had agreed to settle and drop its challenge to the patent at issue. *Tamoxifen*, 466 F.3d at 214; *see Watson Pharms.*, 677 F.3d at 1315 (assuming that non-settling generic companies are equally motivated to "enter the waters by filing their own paragraph IV certifications attacking the patent"); *see also K-Dur*, 686 F.3d at 215 (discussing this misapprehension); *Paying for Delay*, 81 N.Y.U. L. Rev., *supra*, at 1584-85 (same).

As it turns out, the incentive provided by the 180-day period is often necessary to ensure that at least one generic manufacturer has an incentive sufficient to lead it to undertake the risk of challenging the validity of a drug patent. Such challenges are expensive. *See Earning Exclusivity*, 77 Antitrust L.J., *supra*, at 952 (estimating that litigation can cost a generic manufacturer "$10 million or more"). And once there is complete generic market entry, the profit margins might be too slim to justify the risk and expense for any one manufacturer to mount a legal challenge to the patent. *See id.* at 948 n.3 (explaining that up to 80% of a generic drug company's estimated profit on a drug is made during this period of exclusivity) (citing Daniel F. Coughlin & Rochelle A. Dede, *Hatch-Waxman Game-Playing from a Generic Manufacturer Perspective*, 25 Biotech. L. Rep. 525,

525-26 (2006), and Martin A. Voet, The Generic Challenge: Understanding Patents, FDA and Pharmaceutical Life-Cycle Management 61 (2005)); *see also id.* at 952 ("Once multiple generic firms enter the market, prices fall, often dramatically."). The exclusivity period therefore serves as a bounty to overcome a "collective action problem." *Id.* at 953.

To summarize, the 180-day period is an important "carrot, encouraging generic firms to challenge and invalidate bad patents (or invent around them) early and often, and accordingly get generic drugs on the market earlier." *See id.* at 947; *see also* S. Rep. No. 107-167, at 4 (2002) (explaining that the original Hatch-Waxman Act included the 180-day provision to encourage generic manufacturers to "challenge weak or invalid patents . . . so consumers can enjoy lower drug prices"). But it also is important to understand that this carrot is available only to the first generic manufacturer to file a paragraph IV certification. *K-Dur*, 686 F.3d at 204 (citing 21 U.S.C. § 355(j)(5)(D)(iii)). As a result, the statute has been allowed to create a "mismatch between the rights accorded to the first applicants and the first successful challenger," contributing to "an atmosphere in which anticompetitive agreements [a]re entered into between certain pioneer and generic drug firms." 149 Cong. Rec. S16,104, S16,105 (daily ed. Dec. 9, 2003) (statement of Sen. Hatch).

b. Settling drug manufacturers also have structured their settlement agreements, using a so-called poison-pill clause, to actively discourage challenges by non-settling generic manufacturers.

As a further disincentive to challenges by their non-settling rivals, settling drug manufacturers have included within their settlement agreements a clause designed to create a "collective outcome problem" similar to the one that the 180-day exclusivity provision was intended to prevent. Through the typical poison-pill clause, the settling parties agree that the first-to-file generic manufacturer will delay market entry until a specific time, but it may immediately enter the market if another generic manufacturer is successful in challenging the patent at issue as invalid or not infringed. *See, e.g.*, Compl. ¶ 65, J.A. 46 (alleging that the first-to-file generic manufacturer "agreed to refrain from marketing generic AndroGel until August 31, 2015, or earlier if another generic company launched a generic version of AndroGel before that date"); *see also* Br. for Pet. at 52 (explaining that the use of these clauses is "typical" in Hatch-Waxman settlements).

The upshot of such a clause is that it serves as a stick—effectively discouraging *non-settling* generic manufacturers from continuing to maintain challenges to the patent at issue. This is so because, even if a non-settling manufacturer is successful in challenging the patent, the settling first filer can swoop in at the last minute and obtain the benefit of the subsequent challenger's hard work. "As a result,

the patentee can 'buy off' the first generic entrant, paying it to delay entry into the market. Meanwhile, the generic firm retains [in its pocket] the valuable period of exclusivity," effectively scaring off other would-be challengers. *Earning Exclusivity*, 77 Antitrust L.J., *supra*, at 948.

In the end, the use of poison-pill clauses further undermines a key assumption of the scope-of-the-patent test—that non-settling generic manufacturers are still sufficiently motivated to challenge a patent covered by a reverse-payment settlement. *See Watson Pharms.*, 677 F.3d at 1315 (assuming that non-settling generics are equally motivated); *Tamoxifen*, 466 F. 3d at 212-14 (same). These clauses make it economically irrational for non-settling generic manufacturers to continue their own challenges, because they face the immense cost of litigating a patent challenge, along with the certainty that they will not reap the rewards of their labors.

2. Non-Settling Generic Manufacturers Generally Have Not Stepped Forward to Challenge Weak Drug Patents that Are Covered by a Settlement.

Together, the 180-day provision and poison-pill clauses have allowed brand-name manufacturers to successfully discourage subsequent generic manufacturers from challenging the patent, because a later challenger has much less to gain if it litigates its own challenge to judgment. Even assuming that it prevails in the trial court and on appeal, a subsequent challenger is in for a disturbing reward: After shelling out up "$10 million or more" to litigate the case to judgment, *Earning Exclusivity*, 77 Antitrust

L.J., *supra*, at 952, the persistent non-settling generic manufacturer must sit on the sidelines for 180-days, while the settling first-to-file generic manufacturer reaps a period of generic market exclusivity "worth several hundred million dollars." *Paying for Delay*, 81 N.Y.U. L. Rev., *supra*, at 1579. What is more, the settling generic manufacturer can use this period as a head start to negotiate commercial arrangements with large purchasers, locking up sales even after other generic manufacturers enter the market. *Earning Exclusivity*, 77 Antitrust L.J., *supra*, at 953 & n.26. Finally, even after entering the market, the persistent challenger is rewarded with smaller profit margins brought about by the market entry of every other rival generic. *See id.* at 952 n.20 (explaining that, after complete generic market entry, the price of a drug can drop to less than 5% of its original value). For these reasons, a first-to-file generic manufacturer might earn up to 80% of its total profits during the period of generic market exclusivity, *id.* at 948 n.3—profits that are not available to a non-settling generic manufacturer that decides, against economic reason, to persist in its challenge.

Given the wide disparity between monopoly profits and those following complete generic market entry, brand manufacturers are often in a position to literally "pay off a whole series of challengers rather than suffer the possible loss of its patent through litigation." *K-Dur*, 686 F.3d at 215. In addition, because the initial challenger has more to gain than its generic rivals should it pursue its challenge to judgment, *id.*, the brand-name manufacturer pays far less to settle with each subsequent generic challenger, because each subsequent challenger has a dimin-

ished incentive to pursue its case to judgment and, hence, less leverage to command a higher settlement demand, *see Paying for Delay*, 81 N.Y.U. L. Rev., *supra*, at 1586.

It also should come as no surprise that later generic filers have been reluctant to maintain patent challenges in the face of a settlement between the brand-name manufacturer and the first-to-file generic. *See id.* Apotex has provided a rare exception. After the brand manufacturer of the drug modafinil entered into reverse-payment settlements with *four* generic manufacturers that were considered simultaneous first filers challenging the patent, Apotex filed suit under the antitrust laws and stood alone as the only generic manufacturer to challenge the patent to a judgment of non-infringement and invalidity. *See Apotex, Inc.* v. *Celphalon, Inc.*, No. 2:06-cv-2768, 2011 WL 6090696 (E.D. Pa. Nov. 7, 2011), *patent appeal filed*, No. 12-1417 (Fed. Cir.). The modafinil case included unique enticements to a subsequent filer, because: (1) agreements had been reached with *four* "first filers" within a few months, suggesting collusive conduct, and (2) there was evidence (and the district court subsequently found) that the brand-name manufacturer had engaged in a deliberate fraud on the Patent and Trademark Office. This provided additional incentives for Apotex to challenge the patent, because if Apotex proved the patent had been procured by fraud, then it could obtain damages under its antitrust claims, even though the Hatch-Waxman Act provisions gave Apotex no additional reward. But for Apotex's proof of fraud on the Patent and Trademark Office (among other theories of antitrust liability), Apotex would have stood to

gain little to nothing for its efforts in challenging the patent covering modafinil. That is why Apotex's challenge in the modafinil case is the exception, rather than the rule.

B. Heightened Antitrust Scrutiny is Superior to an Approach that Would Effectively Shield Weak Drug Patents From Any Form of Judicial Scrutiny.

The Federal Trade Commission presents a powerful case for why this Court should hold that reverse-payment settlements are presumptively anticompetitive. *See* Br. for Pet. at 19-40. Such a settlement would allow a brand-name drug manufacturer to share monopoly profits with a generic rival, even where the underlying patent would not survive judicial scrutiny. In these circumstances, the settlement agreement operates as a naked restraint of trade—an agreement not to compete. Given the substantial likelihood that these circumstances will actually play out, *see id.* at 6 (explaining that "would-be generic competitors have prevailed nearly three quesers of the time in paragraph IV litigation against brand-name manufacturers" and citing authorities), a reverse-payment settlement should be subject to heightened antitrust scrutiny.

But even putting to one side the legal justifications favoring "quick look" scrutiny over the scope-of-the-patent test, the fact remains that non-settling generic companies are *not* equally motivated to challenge patents covered by reverse-payment settlements—as the court below erroneously assumed. *See Watson Pharms.*, 677 F.3d at 1315; *see also Tamoxifen*, 466 F.3d at 214 (similar). As a result, the scope-

of-the-patent test would not only effectively insulate *reverse-payment settlements* from any form of meaningful antitrust scrutiny, *K-Dur*, 686 F.3d 214, but it also would effectively shield the underlying *patent* from further judicial scrutiny as well. For this reason, the Third Circuit correctly observed that the scope-of-the-patent test "improperly restricts the application of antitrust law *and is contrary to the policies underlying the Hatch-Waxman Act.*" *K-Dur*, 686 F.3d at 214 (emphasis added).

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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AMICUS CURIAE BRIEF

No. 12-416

IN THE

Supreme Court of the United States

FEDERAL TRADE COMMISSION,

Petitioner,

v.

ACTAVIS, INC., ET AL.

Respondents.

On Writ Of Certiorari
To The United States Court Of Appeals
For The Eleventh Circuit

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CORPORATE DISCLOSURE STATEMENT

Bayer Corporation is a wholly-owned subsidiary of Bayer World Investments B.V., a limited liability company formed under the laws of The Netherlands. Bayer World Investments B.V. is a wholly-owned subsidiary of Bayer AG. There is no publicly-held company that owns more than 10% of Bayer AG.

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STATEMENT OF INTEREST OF *AMICI CURIAE* [1]

Bayer AG and Bayer Corporation ("Bayer") are members of the Bayer Group, which develops and manufactures patented pharmaceutical products. The question presented significantly affects Bayer because it is involved in litigation as to those products, and sometimes settles such litigation.

In 1997, Bayer entered into a so-called reverse-payment settlement of litigation concerning Bayer's Ciprofloxacin patent. Various plaintiffs challenged that settlement in several federal and state courts.

Bayer won summary judgment in the consolidated multi-district litigation, based on the "scope of the patent" rule. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 535 (E.D.N.Y. 2005) (*Cipro II*). The Second and Federal Circuits both affirmed, adopting the same reasoning. *See* 604 F.3d 98, 106 (2d Cir. 2010) (*Cipro IV*), *cert. denied*, 131 S. Ct. 1606 (2011); 544 F.3d 1323, 1336-37 (Fed. Cir. 2008) (*Cipro III*), *cert. denied*, 557 U.S. 920 (2009).

This past year, however, the Third Circuit explicitly rejected the scope of the patent rule. *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012). The resulting uncertainty affects Bayer, currently defending a state case challenging the same Cipro settlement. *In re Cipro Cases I & II*, 269 P.3d 653 (Cal. 2012).

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[1] Pursuant to Rule 37.6, *amici curiae* affirm that no counsel for any party authored this brief in whole or in part, and that no person other than *amici* or their counsel made a monetary contribution intended to fund the preparation or submission of this brief. The parties have consented in writing to the filing of this brief.

SUMMARY OF ARGUMENT

1. The scope of the patent rule derives from fundamental principles of antitrust and patent law. Antitrust plaintiffs bear the burden of pleading harm to *lawful* competition. Patent law rewards innovation with a statutory monopoly of limited duration. Thus, in their mutual effort to protect competition, both bodies of law respect an innovator's right to profit by excluding others from invading the boundaries of its patent.

The Court has applied these principles on multiple occasions, including in cases mounting antitrust challenges to patent settlements. In *Bement v. National Harrow Co.*, 186 U.S. 70 (1902), and *Standard Oil Co. v. United States*, 283 U.S. 163, 171 (1931), the Court concluded that the Sherman Act was not intended to prohibit restraints of trade caused by settlement agreements within the scope of a patent holder's right to exclude. The Court did not question the right of the settling parties to provide in their agreements for the full measure of the patent's protection. *Bement*, 186 U.S. at 91 ("that the conditions in the contracts keep up the monopoly ... does not render them illegal"). And, where there was no dispute that the patents were asserted in "good faith," it was unnecessary to resolve any "issues concerning the validity or scope of the cracking patents." *Standard Oil*, 283 U.S. at 181.

Walker Process Equipment, Inc. v. Food Machinery & Chemical Co., 382 U.S. 172 (1965), expanded on these cases, holding that the innovator's protection from antitrust liability might be lost if the patent was procured by fraud, but otherwise that "good faith"

when acting within the patent's scope would furnish a complete defense. *Id.* at 177.

Based on these and other decisions, lower courts have long followed the scope of the patent rule. This rule, which recognizes that there is no harm to competition so long as the challenged conduct is within the scope of a patent and the assertion of the patent is in good faith (that is, not "objectively baseless"), represents the only workable compromise between the innovation and competition fostered by patent and antitrust law. Thus, application of the scope of the patent rule benefits consumers in the long run by protecting both the patentee's and the generic's incentive to bring new drugs to the market.

2. Petitioner's argument entirely ignores the patent holder's right to exclude infringing competition. Under the FTC's proposed standard, the settlement is presumed illegal without regard to the patent merits. That presumption of illegality may be "rebutted," Petitioner claims, but not by any showing that the excluded competition was, in fact, infringing. This theory fails to recognize that, if the Court ignores the right to exclude, most agreements affecting patents, whether settlements or licenses, would be per se illegal market division agreements—including the very term-splitting settlement that the FTC prefers.

Petitioner seeks to cure this flaw in its reasoning by changing the meaning of "competition" in the context of Hatch-Waxman settlements. Petitioner thus assumes that consumers benefit only from accelerated entry of generic drugs, never from preservation of patent rights. That assumption has no support in logic or law. Consumers benefit both

from short-term price declines when *non-infringing* products enter, and from long-term innovation when *infringing* products are excluded.

Petitioner can distinguish the settlements it prefers from those it does not only by employing its one-sided concept of competition. But the merits of the patent claim, which are often uncertain and are the subject of the settlement, determine where consumer interests lie. Courts have therefore concluded that, if the patent claim is not objectively baseless, the tools of antitrust litigation cannot measure the "true" interest of consumers—other than by measuring the scope of the patent. *See* Part I.C, *infra*.

No theory of competitive harm advanced by Petitioner has merit. Though the FTC has changed its theory several times, it now advances its original theory rejected in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), that the settlement actually reached is anticompetitive because a different, term-splitting settlement would have resulted in a longer generic license. The argument is wrong on the facts and the law. It is wrong factually because the pioneer and generic do not value time in the same manner. The argument is fundamentally wrong on the law as agreements are not unreasonably anticompetitive simply because Petitioner can imagine one it finds more competitive. *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 415-16 (2004) (The Sherman Act "does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition."). Petitioner's test renders the

patent holder's right to exclude meaningless and conflicts with established principles of law, including but not limited to the statutory presumption of validity.

*****

In the end, this Court's precedent and basic principles of antitrust law require that the significance of the patentee's right to exclude be accounted for in the antitrust analysis. That alone mandates rejection of the Petitioner's test, which would "undermine the presumption of validity of patents in all cases ..., and would work a revolution in patent law." *Cipro II*, 363 F. Supp. 2d at 529. The decision below should be affirmed.

ARGUMENT

I. THIS COURT'S PRECEDENTS FULLY SUPPORT THE SCOPE OF THE PATENT RULE

A. Fundamental Antitrust And Patent Principles Establish That Agreements, Including Settlements, Within The Scope Of A Patent Cannot Harm Lawful Competition

The antitrust laws and the patent laws each promote competition, but through different means. Antitrust laws protect competition by prohibiting market distortions. *See Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 339 n.8 (1990). Patent laws promote competition by rewarding innovative products with a statutory monopoly of limited duration. U.S. Const., art. I, § 8. Because of their shared pro-competitive vision, both bodies of law respect an inventor's right to profit by actions within the scope of a valid patent.

1. **Antitrust.**

a. Harm to competition is an essential element of any antitrust claim. "The law directs itself not against conduct which is competitive, ..., but against conduct which unfairly tends to destroy competition itself." *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993); *see also* 15 U.S.C. § 45(n) ("The Commission shall have no authority ... to declare unlawful an act or practice ... unless [it] causes or is likely to cause substantial injury to consumers ....").

An antitrust plaintiff bears the burden of pleading and proving competitive harm. "The burden of proof in antitrust cases remains with the plaintiff." *United States v. Arnold, Schwinn & Co.*, 388 U.S. 365, 374 n.5 (1967) (rejecting "a standard of presumptive illegality" urged by the United States), *overruled on other grounds by Cont'l T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36 (1977); *see also Times-Picayune Publ'g Co. v. United States*, 345 U.S. 594, 622 (1953) ("[G]uilt cannot rest on speculation; the Government here has proved neither actual unlawful effects nor facts which radiate a potential for future harm."). The placement of this burden is especially important because the Sherman Act is both a civil *and criminal* statute. *Ill. Tool Works, Inc. v. Independent Ink, Inc.*, 547 U.S. 28, 45 (2006) ("[I]t would be unusual for the Judiciary to replace the normal rule of lenity that is applied in criminal cases with a rule of severity for a special category of antitrust cases."). Any contrary rule would violate the due process principle "that regulated parties should know what is required of them so they may act accordingly." *FCC v. Fox TV Stations, Inc.*, 132 S. Ct. 2307, 2317 (2012).

The plaintiff's burden necessarily includes proof that the allegedly excluded competition is *lawful*. Otherwise, antitrust law is not necessary "to protect the public from the failure of the market," because there is no lawful market. *Spectrum Sports*, 506 U.S. at 458; *see, e.g.*, *In re Canadian Import Antitrust Litig.*, 470 F.3d 785, 790-92 (8th Cir. 2006) (no antitrust liability for precluding illegal importation of drugs); Richard A. Posner, *Economic Analysis of Law* 91 (5th ed. 1998) ("We do not want an efficient market in stolen goods.").[2]

b. These principles apply fully to competition that infringes a valid patent. *Rubber Tire Wheel Co. v. Milwaukee Rubber Works Co.*, 154 F. 358, 364 (7th Cir. 1907) ("[T]he public [i]s not entitled to profit by competition among infringers."); *see Simpson v. Union Oil Co.*, 377 U.S. 13, 24 (1964) ("The patent laws ... are *in pari materia* with the antitrust laws and modify them *pro tanto*.").[3]

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[2] *See also, e.g., RSA Media, Inc. v. AK Media Group, Inc.*, 260 F.3d 10, 15 (1st Cir. 2001) (RSA "was excluded because of the Massachusetts regulatory scheme that prevents new billboards from being built.... Any injury suffered by RSA is therefore unrelated to AK's allegedly exclusionary conduct ...."); *Access Telecom, Inc. v. MCI Telecomms. Corp.*, 197 F.3d 694, 712-13 (5th Cir. 1999) ("If there is no legal U.S. export market ..., then there is no antitrust injury."); *see generally Town of Concord, Mass. v. Boston Ed. Co.*, 915 F.2d 17, 22 (1st Cir. 1990) (Breyer, C.J.) ("An antitrust rule that seeks to promote competition but nonetheless interferes with regulatory controls could undercut the very objectives the antitrust laws are designed to serve.").

[3] *See also, e.g., Hynix Semiconductor v. Rambus*, 527 F. Supp. 2d 1084, 1096 (N.D. Cal. 2007) ("[A]n infringer" has "no legal right to be competing in the product market."); *Monarch Marking Sys., Inc. v. Duncan Parking Motor Maint. Co.*, No. 82C2599, 1988 WL 5038, at *5 (N.D. Ill. Jan. 19, 1988) ("Neither

These principles refute Petitioner's claim that antitrust protects "uncertain" competition as is relevant here. (PB 20-21.) As in the authority Petitioner cites, antitrust only protects competition where there is uncertainty as to the competitor's *likelihood of success* resulting from market factors. But antitrust law simply does not protect competition of uncertain *legality*. *See, e.g.*, *Meijer, Inc. v. Biovail Corp.*, 533 F.3d 857, 864-65 (D.C. Cir. 2008) (affirming dismissal of antitrust complaint because plaintiffs could not show generic competition would have been approved by the FDA); *Maltz v. Sax*, 134 F.2d 2, 5 (7th Cir. 1943) (Antitrust plaintiff who claimed injury in the conduct of unlawful business "had no legal rights to protect.").

2. **Patent.**

"[P]atent law seeks to foster and reward invention." *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979). Thus, "the essence of a patent grant is the right to exclude others from profiting by the patented invention." *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980).

The patent's limited monopoly "is the reward stipulated for the advantages derived by the public for the exertions of the individual, and is intended as a stimulus to those exertions." *Grant v. Raymond*, 31 U.S. (6 Pet.) 218, 242 (1832) (Marshall, C.J.). The right to exclude "serves a very positive function in our system of competition, *i.e.*, the encouragement of investment based risk." *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 876 (Fed. Cir. 1985) (quotation

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[plaintiff] nor consumers have a right to the sale of labels which infringe Monarch's patents.").

marks and citation omitted). Thus, Petitioner's former general counsel warned against ignoring "the first principle that enforcing valid patents makes a major contribution to consumer welfare by providing the incentive for innovation." Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles*, 15 Fed. Cir. B.J. 617, 618 (2006).

"[T]he boundary of a patent monopoly is to be limited by the literal scope of the patent claims." *Dawson Chem. Co.*, 448 U.S. at 221. Within the scope of the patent, however, this Court has held that a patentee is free to maximize its reward, whether by licensing others for profit or refusing to license others to maintain a monopoly. *See, e.g., id.* at 221-23 (holding that refusal to license is not patent misuse and refusing to consider whether "questions of public policy" or "principles of free competition" supported contrary result); *United States v. Gen. Elec. Co.*, 272 U.S. 476, 489 (1926) ("[T]he patentee may grant a license . . . for *any* royalty or upon *any* condition the performance of which is reasonably within the reward which the patentee by the grant of the patent is entitled to secure." (emphases added)).

The patent monopoly is secured through suits for infringement damages and/or an injunction prohibiting further unlawful competition. 35 U.S.C. §§ 271, 283. And, as with all litigation, this Court has recognized a judicial policy favoring settlement of patent suits. *E.g., Standard Oil*, 283 U.S. at 171.

Petitioner offers no reason why a patentee's right to settle disputes should be any more constricted than its right to license. In fact, the ability to settle

patent litigation is such a fundamental part of the right to exclude that the Federal Circuit utilizes control of settlement as an indicia of patent ownership. *See Sicom Sys. Ltd. v. Agilent Techs., Inc.*, 427 F.3d 971, 979 (Fed. Cir. 2005) ("Sicom ... has failed to show that it has all substantial rights under the patent. For instance, Sicom does not have the right to settle litigation ....").

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In their effort to protect innovation and competition, both antitrust and patent law respect a patentee's right to exclude. That is why the Federal Circuit observed that "the outcome is the same whether the court begins its analysis under antitrust law by applying a rule of reason approach to evaluate the anti-competitive effects, or under patent law by analyzing the right to exclude afforded by the patent. The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent." *Cipro III*, 544 F.3d at 1336.

B. This Court's Precedents Protect Agreements Within The Scope of a Patent Asserted In "Good Faith"

Since 1902, this Court has recognized that the antitrust inquiry must account for the patent right to exclude. Three cases in particular are instructive.

1.a. This Court decided *Bement*, 186 U.S. 70, at a time when the per se rule governed all antitrust cases. That case also concerned a challenge to the settlement of patent litigation on terms that maintained the patent monopoly. Consistent with the scope of the patent rule, the *Bement* Court declared that "[t]he first important and most material fact in considering this [antitrust] question

is that the agreements concern articles protected by letters patent." *Id.* at 88.

The patents were important because the "very object of these [patent] laws is monopoly, and the rule is ... that any conditions which are not in their very nature illegal ..., imposed by the patentee and agreed to by the licensee ..., will be upheld by the courts." *Id.* at 91. "The fact that the conditions in the contracts keep up the monopoly ... does not render them illegal." *Id.*

Indeed, *Bement* found the settlement agreements pro-competitive and beneficial. "This execution of these contracts did in fact settle a large amount of litigation regarding the validity of many patents .... *This was a legitimate and desirable result in itself.*" *Id.* at 93 (emphasis added).

Bement thus held that where settlement agreements exclude no more competition than the patent itself, they do not harm lawful competition. "But [the Sherman Act] clearly does not refer to that kind of a restraint of interstate commerce which may arise from reasonable and legal conditions imposed upon the assignee or licensee of a patent ...." *Id.* at 92.

b. In *Standard Oil*, 283 U.S. 163, this Court again considered an antitrust attack on patent settlements. *Standard Oil* explicitly concluded that a settlement of patent disputes "by agreement, rather than litigation, is not precluded by the [Sherman] Act." *Id.* at 171. In so holding, the Court rejected the government's argument that a "division of royalties[] constitutes an unlawful combination," reasoning that "division of royalties are not in themselves conclusive evidence of illegality." *Id.*

The *Standard Oil* Court refused to "consider any of the issues concerning the validity or scope of the cracking patents" because the government failed to cross-appeal the findings that the patentees had acted in good faith. *Id.* at 180-81. Crucial to this point was the master's finding that "the scope of the several groups of patents," however disputed, was sufficient "to justify the threats and fear of litigation." *Id.* Thus, absent a dispute over a patentee's good faith, *Standard Oil* establishes that no antitrust claim lies against a settlement agreement within the scope of the patent.

c. This Court further expanded on the intersection of antitrust and patent law in *Walker Process*, 382 U.S. 172. *Walker Process* represents "[t]he only time the Supreme Court has addressed the circumstances under which the patent immunity from antitrust liability can be pierced" when a patentee's conduct is within the scope of its patent. *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1307 (11th Cir. 2003).

Walker Process sought to achieve "a suitable accommodation ... between the differing policies of the patent and antitrust laws." 382 U.S. at 179 (Harlan, J., concurring). The Court held that proof of actual fraud in securing a patent "would be sufficient to strip [the patentee] of its exemption from the antitrust laws," and thus allow an antitrust claim for wrongful enforcement. *Id.* at 177.

Walker Process stressed, however, that beyond such intentional misconduct in obtaining the patent, the patentee's "good faith would furnish a complete defense" to antitrust claims. *Id.*; *see also, e.g., Globetrotter Software, Inc. v. Elan Computer Group,*

Inc., 362 F.3d 1367, 1375 (Fed. Cir. 2004). And Justice Harlan emphasized that antitrust liability requires actual fraud, not merely invalidity "under one or more of the numerous technicalities attending the issuance of a patent." 382 U.S. at 180 (Harlan, J., concurring).

Together, *Bement*, *Standard Oil*, and *Walker Process* provide the doctrinal basis for the scope of the patent rule: Conduct within the disputed scope of the patent does not violate antitrust laws absent objective baselessness, whether due to fraud on the PTO or sham litigation.

2. Petitioner nonetheless never cites *Bement* and mentions *Standard Oil* and *Walker Process* only once, in passing. (PB 26.) Instead, it seeks solace in other, inapposite precedents.

Petitioner first relies on two cases condemning horizontal agreements between competitors. (PB 20.) Those cases, however, did not involve intellectual property rights that could have precluded competitors from entering the market. *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46 (1990) (agreement to stop selling competing bar review materials); *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150 (1940) (agreement to withdraw surplus spot oil supply from market).

Next, Petitioner provides a string cite of five cases—all without quotation or explanation—in support of the proposition that antitrust law forbids a patentee from inducing others not to infringe. (PB

29.) All of those cases, however, condemned conduct beyond *the scope of the patent* at issue.[4]

Finally, Petitioner uses three precedents to suggest that public policy supports judicial testing of patents. (PB 48.) Each case, however, expressly acknowledged an equal interest in protecting patent holders from infringing competition: "As recognized by the Constitution, [a patent] is a special privilege designed to serve the public purpose of promoting the 'Progress of Science and useful Arts.'" *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945); *see also, e.g., Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892) (recognizing the public importance of protecting the monopoly held by "the patentee of a really valuable invention"); *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 102 (1993) (rejecting Federal Circuit's rule of vacating validity rulings in part because "the patentee may have lost the practical value of a patent

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[4] *United States v. Singer Mfg.Co.*, 374 U.S. 174 (1963) (patent pooling among competitors to create entry barrier); *United States v. New Wrinkle, Inc.*, 342 U.S. 371 (1952) (same); *United States v. Line Material, Co.*, 333 U.S. 287 (1948) (same); *United States v. U.S. Gypsum Co.*, 333 U.S. 364 (1948) (restricting sale of non-patented goods); *United States v. Masonite Corp.*, 316 U.S. 265 (1942) (limiting resale after patent exhaustion).

To the extent these cases are relevant, they provide support for Respondents. For example, *Gypsum* held that the "appeal must be considered on a record that *assumes the validity of all the patents involved*." 333 U.S. at 388 (emphasis added). Likewise, Justice White's concurrence in *Singer* makes plain that the condemned actions included a conspiracy to defraud the PTO—conduct also forbidden by the scope of the patent rule. *See* 374 U.S. at 200 (White, J., concurring).

that should be enforceable against different infringing devices").[5]

C. Until *K-Dur*, The Lower Courts Properly And Consistently Applied The Scope Of The Patent Rule

Lower courts have consistently and correctly held that, when patents are involved, "the protection of the patent laws and the coverage of the antitrust laws are not separate issues." *United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1128 (D.C. Cir. 1981) (discussing *Bement*, 186 U.S. at 91).

Years before the first antitrust challenges to Hatch-Waxman settlements, the rule was settled that antitrust analysis of patent agreements must always begin with the patent's exclusionary effect. *Id.* ("[T]he conduct at issue is illegal if it threatens competition in areas other than those protected by the patent, and is otherwise legal."); *accord, e.g.*, *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 703, 708 (Fed. Cir. 1992) (citing *Bement* and holding "[s]hould the restriction be found to be reasonably

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[5] Petitioner's suggestion that the Hatch-Waxman Act reflects a "strong congressional policy ... favoring testing the scope and validity of pharmaceutical patents," (PB 48), is inaccurately one-sided. As other courts have recognized, the statute attempted "to strike a balance *between two conflicting policy objectives*: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling" generic competition. *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 230 (4th Cir. 2002) (quotation marks and citation omitted; emphasis added). Senator Hatch himself has therefore criticized Petitioner's proposed standard, noting that it could "effectively discourage pro-consumer settlements." S. Rep. No. 111-123, at 23 (2010).

within ... the scope of the patent claims, that ends the [antitrust] inquiry"); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1204, 1206 (2d Cir. 1981) (citing *Bement* and concluding "where a patent has been lawfully acquired, subsequent conduct permissible under the patent laws cannot trigger [antitrust] liability"); *see USM Corp. v. SPS Techs., Inc.*, 694 F.2d 505, 513 (7th Cir. 1982) (Posner, J.) (Antitrust liability may lie "only upon proof of an anticompetitive effect beyond that implicit in the grant of the patent.").

Bayer's *Cipro* case was among the first to apply these principles to reverse-payment settlements. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 249 (E.D.N.Y. 2003) (*Cipro I*). ("[T]he proper analysis in this case is whether the ... challenged agreements restrict competition beyond the exclusionary effects of the [Cipro] patent."). Citing *Bement* three times, and *Walker Process* thirty-three, the district court concluded: "Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent." *Cipro II*, 363 F. Supp. 2d at 535.

Cipro I recognized that application of the scope of the patent rule was especially appropriate in light of the incentive structure created by Hatch-Waxman. 261 F. Supp. 2d at 252.[6] The Solicitor General

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[6] By creating a "highly artificial" act of infringement without damages, Hatch-Waxman created an incentive to initiate even marginal lawsuits. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990); *See* Kelly Smith & Jonathan Gleklen, *Generic Drugmakers Will Challenge Patents Even When They Have a*

previously agreed. *See* Brief for United States as *Amicus Curiae* at 9-10, *Joblove v. Barr Labs., Inc.*, 551 U.S. 1144 (2007) (No. 06-830) ("*Tamoxifen* Br.") ("A patent holder may enter into such a settlement even if it believes that the likelihood that its patent will be held invalid is relatively small, out of concern that it would suffer enormous consequences in the event of invalidation.").

Seven federal appellate opinions have explicitly approved *Cipro*'s reasoning, with six rejecting antitrust claims because the settlements were within the patent's exclusionary effects. *E.g.*, *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1313 (11th Cir. 2012); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006); *Schering-Plough*, 402 F.3d at 1068; *Valley Drug*, 344 F.3d at 1306; *cf. In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 907-08 nn.12-13 (6th Cir. 2003) (expressly distinguishing *Cipro* and finding liability because the settlement in *Cardizem* imposed restraints beyond the exclusionary effect of the patent).

97% Chance of Losing, 9 CPI Antitrust Chron. 1, 1-2 (2012). Thus, "Hatch-Waxman creates a context in which payments from the patent owner to the infringer become explicit *rather than implicit*, but it does not ... make them more anti-competitive than such payments in the traditional context." Bernard & Tom, *supra*, 15 Fed. Cir. B.J. at 621 (emphasis added).

II. PETITIONER'S THEORIES OF COMPETITIVE HARM IGNORE THE PRO-COMPETITIVE EFFECTS OF PATENT RIGHTS, CONFLICT WITH ESTABLISHED PRINCIPLES OF LAW, AND WOULD REPEAL THE STATUTORY PRESUMPTION OF VALIDITY

Petitioner's proposed standard elides the central focus of appropriate antitrust analysis in this context—the patent. In stark contrast to the scope of the patent test, the right to exclude plays no role in Petitioner's proposed presumption of illegality and no role in Petitioner's proposed methods of rebutting that new presumption.

Thus, Petitioner's proposed standard raises two fundamental questions: Can antitrust law ignore patent rights when assessing harm to lawful competition? And if not, can any test other than the scope of the patent rule properly account for the effect of the patent?

The relevant statutory language, this Court's precedents, and simple logic all dictate that the answer to both questions is no.

A. Any Antitrust Analysis of Patent Settlements Must Account For The Patent Holder's Right To Exclude

1. Petitioner seeks to impose a presumption of illegality on all "settlements that involve a reverse payment (*or its functional equivalent*) from the plaintiff to the defendant." (PB 46 (emphasis added).) That is, to trigger the presumption of illegality, a plaintiff need only show the presence of a reverse payment. (*Id.*) The patent merits are then to be ignored. (PB 53-55.) Like the court in *K-Dur*,

Petitioner contends that "there is no need to consider the merits of the underlying patent suit." *K-Dur*, 686 F.3d at 218. Thus, the patentee would be precluded from even asserting validity or infringement as defenses to antitrust claims. (*See* PB 37-39 (recognizing "two primary ways in which the parties to a reverse-payment settlement ... could rebut the presumption," neither of which have to do with the patent merits).

The fundamental fallacy in any antitrust standard that ignores the patentee's right to exclude is that the existence of that right is usually the *only* reason that patent agreements are legal in the first place. Indeed, in the absence of the right to exclude, most patent agreements—including virtually all licenses—would be illegal. *Studiengesellschaft*, 670 F.2d at 1128 ("[A] patent by definition restrains trade, and in effect makes most exclusive patent licenses *per se* violations of the antitrust laws."); *see generally* XII Herbert Hovenkamp, *Antitrust Law* ¶ 2040b (2d ed. 2005) ("[Licensing] agreements would generally be classified either as per se unlawful naked price fixing, or as per se unlawful naked horizontal market divisions" in the "absence of a patent." (footnote omitted)).

As the Eleventh Circuit explained in *Valley Drug*, the patent is not merely the central focus of the inquiry; it is usually the only thing that matters:

> If this case merely involved one firm making monthly payments to potential competitors in return for their exiting or refraining from entering the market, we would readily affirm the district court's

> order. *This is not such a case, however, because one of the parties owned a patent.*

344 F.3d at 1304 (emphasis added).[7]

The decision in *Studiengesellschaft* made the point expressly. In that case, because the district court had conducted a rule of reason analysis that ignored "the scope of patent protection, ... its method of analysis had the effect of applying a *per se* rule." 670 F.2d at 1128. That was reversible error, "because once the protection of the patent was removed, the license conditions, like the patent itself, inevitably had the effect of restricting competition." *Id.* So, too, Petitioner's standard here "in effect makes most exclusive patent licenses *per se* violations of the antitrust laws." *Id.*

Petitioner ignores the implications of its standard for patent licenses, but offers no reason in logic or law for limiting its rule to agreements that happen to arise from patent litigation within the pharmaceutical industry. Indeed, Petitioner could just as easily attack the terms of a patent license on the grounds that, without those terms, the licensed-entry date may have been earlier. Yet such restrictions on the right to exploit the patent right would be directly contrary to law. *See Brulotte v. Thys Co.*, 379 U.S. 29, 33 (1964) ("A patent empowers the owner to exact royalties as high as he can

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[7] Even former FTC Commissioner Leary recognized that "*[i]f a patent is valid*, the pioneer manufacturer is entitled to its monopoly profit, and a settlement that merely transfers a portion of that profit to a potential generic manufacturer causes no harm." Thomas B. Leary, *Antitrust Issues in Settlement of Pharmaceutical Patent Disputes*, 14 ABA Antitrust Healthcare Chron. 1, 6 (Winter 2000/2001) (emphases added).

negotiate with the leverage of that monopoly."); *Gen. Elec. Co.*, 272 U.S. at 489 ("[T]he patentee may grant a license ... for *any* royalty or upon *any* condition the performance of which is reasonably within the ... patent" (emphases added)).

Judge Trager recognized that Petitioner's proposed standard would threaten all patent agreements, regardless of the method of compensation or industry:

> If the settlement with a payment to a generic is to be subject to antitrust liability, ... the next antitrust challenge to a patent settlement might well take place in the context of a license with royalty .... To open royalty-bearing patent license agreements to antitrust scrutiny simply because patents are often held invalid ... would undermine the settled expectations of patentees and potential infringers/licensees across countless industries.

Cipro II, 363 F. Supp. 2d at 533. This lack of any limiting principle explains why no court, not even *K-Dur*, has accepted Petitioner's proposed standard wholesale.[8]

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[8] Even *K-Dur*, which adopted Petitioner's rule of presumptive illegality, carefully limited its holding to (1) cash payments, and (2) the pharmaceutical context. "We caution that our decision today is limited to reverse payments between patent holders and would be generic competitors in the pharmaceutical industry." 686 F.3d at 216. Thus, district courts in the Third Circuit have appropriately rejected—over the FTC's objection—arguments seeking to apply a presumption of illegality to settlements involving other forms of compensation, including the venerable exclusive license. *See, e.g.*, *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 2:12-cv-0995, 2012 WL 6725580, at *6 (D.N.J. Dec. 6, 2012) ("[T]he term 'reverse payment' is not

2. Recognizing the fundamental point that agreements within a patent's scope are either lawful under the antitrust laws based on the right to exclude or unlawful, has several consequences for Petitioner's proposed standard.

Initially, it demonstrates that the existence or non-existence of money or other consideration in a settlement is beside the point: "The failure to produce the competing ... drug, rather than the payment of money, is the exclusionary effect." *Valley Drug*, 344 F.3d at 1309. Even without payments, "the parties ... could settle on an early entry date *with a license calibrated to achieve a similar financial result to the parties as an exclusion payment*." *Cipro II*, 363 F. Supp. 2d at 537 (emphasis added). The antitrust question remains whether the excluded entry can be proven lawful. If the generic was infringing, no amount of money can make its exclusion harmful; if it was not infringing, no absence of money can make its exclusion helpful to consumers.

The same principle renders inapt the petitioner's repeated assertions that a settlement with reverse payments "resembles" or is "similar" to classical market-division agreements. (PB 15, 19-20, 34-35.) The critical difference, as these courts noted, is that "one of the parties owned a patent" *Valley Drug*, 344 F.3d at 1304. The central precedent on which Petitioner relies, *Palmer*, 498 U.S. 46 (PB 20), underscores the difference. In that case, the parties

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sufficiently broad to encompass any benefit ... to [the generic] in a negotiated settlement."); *see Prof'l Drug Co. v. Wyeth Inc.*, No. 3:11-cv-05479, 2012 WL 4794587, at *2 (D.N.J. Oct. 3, 2012) (denying FTC motion to file *amicus* brief).

had competed head-to-head in the same market area for years. There was no suggestion that anyone's intellectual property rights precluded such competition in any way. The parties' later decision to share one of their trademarks was thus irrelevant to the existence of the prior competition they unlawfully agreed to end. *Id.* at 48-49.

Similarly, Petitioner's suggestion that the Court apply heightened antitrust scrutiny in a "quick look" analysis misses the point. This Court undertakes "quick look" antitrust scrutiny only where "the great likelihood of anticompetitive effects can be easily ascertained," or "a confident conclusion about the principal tendency of a restriction may be drawn." (PB 34 (quoting *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 770-71 (1999)). That condition obviously cannot be met when, without resolving the patent claim merits, we do not know that the settlement threatened competition *at all*.

The quick look approach, moreover, is "reserved for circumstances in which the restraint is sufficiently threatening to place it presumptively in the per se class, but *lack of judicial experience* requires at least some consideration of proffered defenses or justifications." X Areeda et al., *supra*, ¶ 1911a. It would be particularly anomalous to apply quick look scrutiny where, but for the *K-Dur* decision, the overwhelming weight of judicial experience has rejected Petitioner's proposed rule, and instead embraced the scope of the patent test. *See supra*, § I.C.

The absence of any consensus that settlements with payments are highly likely to be anticompetitive may be best reflected in the inconsistent positions

that the Solicitor General has taken before this Court. The Solicitor General previously explained that there was no doctrinal foundation for use of quick look scrutiny. "[T]he public policy favoring settlements, and the statutory right of patentees to exclude competition within the scope of their patents, would potentially be frustrated by a rule of law that subjected patent settlements involving reverse payments to automatic *or near-automatic* invalidation." Brief for the United States as *Amicus Curiae* at 10-11, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273) (emphasis added) ("*Schering-Plough* Br."). He now acknowledges the inconsistency (PB 41 n.9), but this change of heart is reason alone to conclude that the settlements he now opposes are not "obviously" anticompetitive.[9]

Finally, reviewing the history of litigated reverse settlements provides no support for the proposition that such settlements invariably delay generic competition. In the *Cipro* cases, Bayer's compound patent was validated on reexamination by the PTO and in three subsequent generic challenges litigated to judgment. *See Cipro II*, 363 F. Supp. 2d at 530 n.14. The same occurred in *Tamoxifen*: following the settlement, Zeneca defeated three subsequent generic patent challengers. 466 F.3d at 195. In both cases, the settlements allowed early entry that litigation of the patent right would have foreclosed.

Even in a case where a settlement went beyond the scope of the patent—and thus was held to constitute

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[9] To be sure, the former Solicitor General suggested that some showing less than objective baselessness would suffice. Such an argument has been abandoned by Petitioner here and, in any event, fails for the reasons explained *infra*, § II.B.3.

a *per se* antitrust violation—the FTC itself *still* failed to find any harm to competition. "[I]t does not appear that there was any delay in the entry into the market ... , or that the conduct or agreement at issue delayed consumer access to a generic version of Cardizem CD." *In re Hoechst Marion Roussel, Inc.*, 131 F.T.C. 925, 955 (2001); *see also, e.g., Kaiser Found. Health Plan, Inc. v. Abbott Labs., Inc.*, 552 F.3d 1033, 1041 (9th Cir. 2009) (jury verdict of $0 damages from Hytrin settlement).

In sum, Petitioner's attempt to extract the only important competitive factor from the analysis of patent settlements—the right to exclude—must fail.[10] Along with it goes Petitioner's strained attempt to analogize (i) time-honored licensing agreements that allocate patent rights to (ii) per-se illegal horizontal agreements that allocate markets.

B. Petitioner's Theories Of Competitive Harm, Which Seek To Redefine Competition, Are Unsupported In Logic And Contrary To Law

In attempting to articulate a theory of harm to competition, Petitioner posits a competitive "ideal" in which the settling parties agree only upon an entry date for the generic product:

> When the parties to a Hatch-Waxman settlement simply agree upon a

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[10] To make this error more palatable, Petitioner suggests in a footnote that it may in fact be necessary to address the patent merits for "[q]uantification of damages in a private antitrust action." (PB 55 n.11.) But Petitioner neglects to see that the alleged injury here, both to competition and to any individual purchaser, has the same source: the exclusion of the generic product. If that exclusion was justified by the merits of the patent claim, there is no harm to lawful competition at all.

> compromise date of generic entry, with no money or similar consideration flowing from the brand-name to the generic manufacturer, the settlement is unlikely to raise antitrust concerns.

(PB 27.)

The first difficulty with this ideal, as Petitioner concedes, is that, if the patent is to be ignored, such term-splitting would also be a market division agreement. (PB 27-28 ("[S]uch a compromise settlement of paragraph IV litigation will entail the parties' agreement not to compete.").) That is, Petitioner's ideal settlement also "delays" generic entry by definition and "resembles" classical market division agreements to the same extent as those with reverse payments. Thus, to save its preferred settlement method from its own presumptive illegality standard, the FTC must redefine protected competition solely for purposes of Hatch-Waxman settlements. This attempt fails.

1. Petitioner's argument depends on the critical, and unsupported, assumption that, in the course of private patent litigation, the competitive interest of consumers *always* favors generic entry and lower drug prices. Petitioner thus asserts that a settlement negotiation strictly limited to a generic entry date "has the practical effect of aligning [the generic's] interests in paragraph IV litigation with those of consumers, who benefit from the lower prices that generic competition provides." (PB 28.) This view, however, "ignores the first principle that enforcing valid patents makes a major contribution to consumer welfare." Bernard &. Tom, *supra*, 15 Fed. Cir. B.J. at 618.

Indeed, the patentee's right to exclude is not simply beneficial, but *procompetitive*. It is widely recognized that the existence and protection of valid patent rights "driv[e] economic growth and increas[e] consumer welfare." Charles F. Rule, *Patent-Antitrust Policy: Looking Back and Ahead*, 59 Antitrust L. J. 729, 730 (1991) (comments of former Assistant Attorney General for the Antitrust Division); *Loctite Corp.*, 781 F.2d at 876. (right to exclude infringers "serves a very positive function in our system of competition").[11]

Accordingly, settlements that protect that right benefit consumers. *See* Bernard & Tom, *supra*, 15 Fed. Cir. B.J. at 622 ("[I]f *the settlement* prevents infringing entry, such prevention in itself is a *pro-competitive* effect." (first emphasis added)). The Solicitor General has made the same point to this Court. *Tamoxifen* Br. at 8-9 ("[L]egitimate patent settlements ... further the important goals of encouraging innovation and minimizing unnecessary litigation."). And even Petitioner concedes that

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[11] This Court has observed that "[d]evelopment of new uses for existing chemicals .... is extraordinarily expensive. It may take years of unsuccessful testing before a chemical having a desired property is identified, and it may take several years of further testing before a proper and safe method for using that chemical is developed." *Dawson Chem.*, 448 U.S. at 221-22 (1980). More so for chemicals for human use: "To be deemed 'safe and effective' and thereby obtain FDA approval, a new drug must undergo an extensive application and approval process.... The test is rigorous, requiring expensive and time-consuming clinical trials estimated by some to cost more than $800 million per drug." *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 388-89 (5th Cir. 2008) (quotations and footnotes omitted).

"preserv[ing] the incentives to innovate ... benefit[s] consumers in the long run." (PB 45.)

As a result, Petitioner's theory of harm fails in its underpinnings: "It is inappropriate to use an analytical model in which the benefits of price competition on one side of the equation are taken into account, but the benefits of innovation on the other side of the equation are not." Bernard & Tom, *supra*, 15 Fed. Cir. B.J. at 621. If that mistake is made, "it is easy to get to a conclusion of presumptive illegality." *Id.* at 622.

2. Petitioner thus argues that reverse payments are unlawful, because a term-splitting settlement would produce a longer license and hence be better for consumers. (PB 40 ("[T]he parties may settle with an earlier entry date and no reverse payment, which would benefit consumers ....").)

a. As a legal matter, this conclusion is irrelevant. Antitrust liability does not attach simply because a court can hypothesize a "better" settlement than the one actually reached. *Verizon*, 540 U.S. at 415-16 (2004) ("The Sherman Act ... does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition." (internal quotation marks and citation omitted)); *Am. Motor Inns, Inc. v. Holiday Inns, Inc.*, 521 F.2d 1230, 1249 (3d Cir. 1975) ("Application of the rigid 'no less restrictive alternative' test in cases such as this one would place an undue burden on the ordinary conduct of business."); *see also Buffalo Broad. Co. v. ASCAP*,

744 F.2d 917, 933 (2d Cir. 1984) (similar). [12] Accordingly, as long as the settlement excludes no more competition than does the patent itself, "consumers have no right to second-guess whether some different agreement would have been more palatable." *Cipro II*, 363 F. Supp. 2d at 536 (citing *Trinko*, 540 U.S. at 415-16).

Petitioner has no persuasive response to Judge Posner's point that the assumption of competitive harm from reverse payments "may be doubted, since if settlement negotiations fell through and the patentee went on to win his suit, competition would be prevented to the same extent." *Asahi Glass Co v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 989, 994 (N.D. Ill. 2003) (Posner, J., by designation).

b. As a matter of fact, moreover, the "better settlement" presumption is simply false. Even Petitioner admits that settlement is not always possible when negotiations are limited to the date of generic entry. (PB 40 ("To be sure, ... a rule discountenancing reverse payments may cause the parties to litigate to judgment.").)

Generic and branded companies value the time period of a license differently. Due to the difference in prices charged, the time-value of a license to the generic is much less than the amount the brand-name manufacturer would have to sacrifice. In such a case, money can bridge the gap, making a settlement possible where negotiating only on the

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[12] *Trinko*'s rule applies with especial force where Petitioner's proposed solution—requiring an earlier license—is itself contrary to the patent statute. *See* 35 U.S.C. § 271(d)(4) (providing that "refus[al] to license" is not patent misuse).

length of the license would not. *See, e.g.*, Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 Antitrust L.J. 1033, 1062 (2004).

It thus is incorrect to say that the money caused the entry date to be delayed: without the payment, there would be no settlement (and no early licensed entry) at all. *Cf.* Brief for United States and FTC as *Amicus Curiae* at 9, *Andrx Pharms., Inc. v. Kroger Co.*, 543 U.S 939 (2004) (No. 03-779) ("Cardizem Br.") ("Reverse payments may have the salutary effect of facilitating efficient settlements that advance consumer welfare.").

3.a. In advancing its "better settlement" theory, Petitioner reverts to its original rationale for attacking reverse payments that the Eleventh Circuit rejected in *Schering-Plough*, 402 F.3d 1056. When the FTC sought certiorari in that case, however, it adopted a new rationale, described by the Solicitor General as follows: "The FTC's petition emphasizes what it calls the "'probabilistic' nature of the property interest created by the patent laws" and the view that "a patent is not a right to exclude, but rather a right to *try* to exclude." *Schering-Plough* Br. at 11.

This so-called "probabilistic" patent theory sought to create a consumer right to the *potential* invalidation of the patent. *See* Petition for Certiorari at 10-11, 18, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273) (if the patent had a 50% chance of defeat, the settlement would cause consumers to "lose the 50 percent chance they had of enjoying the benefits of competition."). The FTC has wisely abandoned this theory here, for "there is no support in the law for such a" "concept of a public

property right in the outcome of private lawsuits." *Cipro II*, 363 F. Supp. 2d at 531; *see also, e.g.*, *Nestle Co. v. Chester's Market, Inc.*, 756 F.2d 280, 284 (2d Cir. 1985) ("We see no justification to force these defendants, who wish only to settle the present litigation, to act as unwilling private attorneys general and to bear the various costs and risks of litigation," which include "the non-trivial risk of" exclusion by unfavorable judgment).

b. Nor does Petitioner substantively advance the argument of the Justice Department in the *Cipro* case, which bases the injury to competition on the subjective expectation of the parties as to how the litigation might turn out, *i.e.*, "the amount of competition anticipated by the parties to the patent litigation." (PB 16); *see* U.S. Br. at 24, *Cipro IV*, 604 F.3d 98 (No. 05-2851) (filed July 6, 2009). Such a subjective standard would turn an antitrust violation into a thought crime whereby a bashful patentee, who fears that he is likely to lose, must choose a settlement that transfers far more value to consumers than that of a recklessly confident patent holder.

Among many other flaws, neither the "expected value" nor the "probabilistic property" theories has anything to do with payments, reverse or otherwise. Every settlement deprives consumers of the chance that the patent will be defeated—whether that chance is measured objectively (the "probabilistic property" theory) or subjectively (the "expected value" theory).

c. The FTC also advanced a new theory below, arguing that it should be permitted to show only that the defeat of the patent was "likely." Although not

advocated here, any such 'likely' winner legal standard merely raises the question: What degree of likely success is sufficient for a patentee to avoid antitrust liability? 30%? 50%? More? And how can a lay jury with no patent training determine those odds?

Indeed, "[i]t is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case." *Whitmore v. Arkansas*, 495 U.S. 149, 159-60 (1990); *see also, e.g.*, *Christianburg Garment Co. v. EEOC*, 434 U.S. 412, 422 (1978) ("[S]eldom can a prospective plaintiff be sure of ultimate success .... [T]he course of litigation is rarely predictable.").

Courts adjudicating challenges to Hatch-Waxman settlements have accordingly rejected a 'likely' winner standard. *See, e.g.*, *Valley Drug*, 344 F.3d at 1308 ("Patent litigation is too complex and the result too uncertain for parties to accurately forecast ....").

C. Acceptance Of The FTC's Standard Would Repeal The Presumption Of Validity

Petitioner's standard would also effectively repeal Congress's decision to afford patents a statutory presumption of validity. "A patent shall be presumed valid .... The burden of establishing invalidity ... shall rest on the party asserting such invalidity." 35 U.S.C. § 282.

Just two terms ago, this Court confirmed that this statute is more than a simple procedural device. *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2247 (2011) ("[W]e cannot accept Microsoft's argument that Congress used the words presumed valid to adopt only a procedural device for shifting the burden of production or ... the burden of persuasion." (quotation marks omitted)). In its

recent *K-Dur* decision, the Third Circuit simply got this wrong. *K-Dur*, 686 F.3d at 214 ("[T]his presumption is intended merely as a procedural device ....").

Instead, the presumption of validity has a long common-law heritage. As early as 1934, this Court held that a "patent regularly issued, and even more obviously a patent issued after a hearing of all the rival claimants, is presumed to be valid *until the presumption has been overcome by convincing evidence of error.*" *Radio Corp. of Am. v. Radio Eng'g Labs., Inc.*, 293 U.S. 1, 7 (1934) (emphasis added). Nor is there any doubt that the presumption applies in antitrust cases. *See Standard Oil*, 283 U.S. at 181 (where good faith of patent claim was uncontested, presumption of validity applied in full).

Petitioner's only response to the presumption of validity is to note that the presumption can be rebutted. (PB 26.) But Petitioner's proposed standard does not require antitrust plaintiffs to rebut the presumption at all. Petitioner's standard does not allow the validity of the patent to become relevant at any stage. Under Petitioner's standard, therefore, the rebuttable statutory presumption of validity is converted to an irrebutable presumption of patent invalidity. Because the FTC intends its standard to govern all cases, the FTC's presumption of illegality will have the effect in numerous cases of contradicting the presumption of validity that Congress duly enacted.

For example, where an innovator holds a patent on a drug's active pharmaceutical compound, the ANDA applicant must necessarily admit infringement in order to claim bioequivalence as required by statute.

See 21 U.S.C. § 355(j)(2)(A); *Cipro II*, 363 F. Supp. 2d at 518 ("[B]ecause Barr was required in its ANDA to certify that its generic version of Cipro was bioequivalent to Bayer's Cipro, there is no dispute that Barr's product would have infringed Bayer's patent."). In such cases, validity is the only disputed patent issue. The settling parties should be entitled to rely on Congress's decision to treat patents as presumptively valid without fear of presumptive antitrust liability.

Permitting liability on any lesser showing, in contrast, would create an antitrust claim based on the exclusion of *unlawful* competition. For example, Petitioner's standard could treat the Cipro settlement as presumptively unlawful, even though the Federal Circuit (twice), three district courts, and the PTO all reaffirmed the patent. *See Cipro II*, 363 F. Supp. 2d at 530 & n.14 ("[T]here is something anomalous about the notion that plaintiffs could collect treble damages for settlement of a litigation involving a patent that has been subsequently upheld by the Federal Circuit.").[13]

The presumption of validity is not the source of the scope of the patent rule, which is grounded in basic principles of antitrust and patent law. *See, e.g.*, *Tamoxifen*, 466 F.3d at 209 n.22 ("[I]rrespective of

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[13] The Direct Purchasers' *amicus* brief suggests that Bayer won these later cases because the challengers lacked time to raise inequitable conduct as a defense. (DP Br. at 7-8.) "But this argument is not very convincing in light of the fact that one of the challenges—Carlsbad's, on the ground of obviousness—also required extensive discovery and resulted in a nine-day bench trial." *Cipro II*, 363 F. Supp. 2d at 530; *aff'd*, *Cipro III*, 544 F.3d at 1341 ("[W]e agree[] that no fraud occurred.").

whether there was a presumption or where any such presumption lay at the time of settlement, we think that Zeneca was then entitled to protect its tamoxifen patent monopoly through settlement."). But the presumption of validity is most assuredly another legal principle that acceptance of Petitioner's proposed standard would violate – and another reason why a standard wholly ignoring a patentee's right to exclude cannot stand.

CONCLUSION

The Court should affirm the judgment below.

Respectfully submitted,

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ACTAVIS, INC., *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

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STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

Amici curiae are law professors who teach patent law and antitrust law, and have published articles in several law reviews discussing antitrust law, particularly as it relates to Hatch-Waxman litigation. Various forms of pro-competitive settlements are often entered in patent disputes, particularly under the Hatch-Waxman Act. *Amici* are exceptionally familiar with both patent and antitrust laws, and have an interest that these laws be applied properly, pursuant to the prescriptions of Congress and this Court, and in a manner that does not frustrate key purposes of the patent system and the Hatch-Waxman Act.

SUMMARY OF ARGUMENT

Settlement of disputes in the context of patent litigation, including Hatch-Waxman litigation, as in the context of any other type of litigation, is commonplace, encouraged, and promotes judicial economy. So-called reverse payment settlements, with the patentee paying money or some other compensation to the alleged infringer, raise complex issues, and their effects on innovation, competition and consumer welfare are not easily assessed.

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1. No counsel for a party authored this brief in whole or in part and no party of counsel for a party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amici curiae* or their counsel made a monetary contribution to its preparation or submission. The parties have all either filed blanket waivers with the Court or have explicitly consented to the filing of this brief.

The Hatch-Waxman Act was intended to preserve incentives for innovation by lengthening the effective term of pharmaceutical patents to encourage innovation, while also facilitating generic entry where appropriate through an expedited regulatory approval process, an ability to challenge patents without risking the huge damages entailed in infringing market entry in the face of litigation uncertainty, and incentives to generic manufacturers to be the first to submit a non-infringing generic. Reverse payment settlements may serve the purposes of the Hatch-Waxman Act, allowing private parties to discount litigation risks and agree upon a solution which preserves the incentive for innovation in the patent, while allowing generic entry earlier than likely would have been the case in the absence of the settlement.

Legislation passed by Congress in 2003 requires that all Hatch-Waxman Act patent settlement agreements be filed with the FTC. However, Congress has repeatedly decided not to pass legislation encouraged by the FTC that would either make reverse payment settlements per se illegal or presumptively illegal.

A patent grants a right for a limited term to exclude competition, and once the USPTO examines the patent application and determines to issue a patent, the Patent Act grants the patent a presumption of validity in any litigation challenging the patent. Anyone suggesting that a patent has been asserted or enforced in bad faith must first allege and establish, under the precedent of this Court, that the action was so objectively baseless that no reasonable patentee could realistically expect success on the merits.

The FTC suggests that any delay of generic entry pursuant to a reverse payment settlement agreement – no matter what the chances of success of the alleged infringer in the underlying litigation – causes harm to competition. The courts, for the most part, have disagreed with that analysis. Why? First, there can be no adverse effect on competition by delaying generic entry that never would have occurred without the settlement because the patentee would have won the underlying patent litigation. Second, the settlement's clearing of the patent dispute typically allows generic entry prior to the expiration of the patent, providing assured competition, where competition was doubtful or uncertain prior to the settlement. Third, and perhaps most important, the patentee's preservation of its presumptively valid patent provides funding as an incentive for innovation, which benefits competition and consumer welfare, as contemplated under the Constitution, the Patent Act, and the Hatch-Waxman Act.

To the extent the FTC presumes that such settlements may sometimes protect patents that would be found invalid if subject to further analysis, the Patent Act provides a more appropriate avenue for relief than broad condemnation under the antitrust laws of settlements that may be pro-competitive. Congress has provided and recently enhanced multiple low-cost appropriate fora for policing the validity of issued patents, including reexamination and other proceedings before the USPTO, with appeals to specialized expert institutions specifically established by Congress to address interpretation and validity of patents.

In sum, neither the competitive effects of the settlement nor the strength of a patent can be assessed

from the mere existence of some arguable "reverse payment" in a Hatch-Waxman patent litigation settlement. The scope of the patent and the merits of the underlying patent case cannot be ignored in assessing competitive effects. Nor can the pro-competitive effects of preserving the incentives to innovate established in the patent. The USPTO, the Board of Patent Appeals and Interferences and the Federal Circuit are better equipped to address weak patents than antitrust challenges through the several Courts of Appeal with no expertise in patents. Incentives for innovation and for early generic entry would be destroyed and consumer welfare lost by any presumption that such agreements were illegal.

ARGUMENT

I. Nothing in the Structure or Purpose of the Hatch-Waxman Act Is Intended to Change the Rules Governing Patent Litigation Settlements.

The Hatch-Waxman Act did not change the way patent cases could be settled, nor did it change the burdens of proof in patent litigation. *See* H.R. Rep 98-857, pt.1, at 28 (1984). The Act was not designed to undercut protection of the innovator's exclusive right. *See* 130 Cong. Rec. 24,427 (September 6, 1984) (Congressman Waxman). *See also Abbott Laboratories v. Young*, 920 F.2d 984, 985 (D.C. Cir. 1990) ("The statute created a new system for protecting both the interests of drug manufacturers who produce new drugs and the interests of generic drug manufacturers and their consumers.") To suggest that reverse payment settlements undermine the efforts of Congress in enacting the Hatch-Waxman Act is at odds with both the letter and spirit of the Act.

A. Settlements in All Patent Cases Are Favored, Common, and Often Involve What the FTC Characterizes Here as "Reverse Payments."

As with any litigation, settlement of patent suits is not unusual. Between 80% and 95% of such suits are settled. *See* Matthew J. Higgins & Stuart J. H. Graham, *Balancing Innovation and Access: Patent Challenges Tip the Scales*, 326 SCIENCE 370, 370 (2009); Schildkraut, *Patent Splitting Settlement and the Reverse Payment Fallacy*, 71 Antitrust Law Journal 1033, 1048 (2004). Unlike accused infringers in other contexts, however, ANDA filers typically have no damages exposure, and nothing to lose other than the costs of litigation. The unique position that ANDA filers have in Hatch-Waxman litigation encourages Paragraph IV certifications, and persistent litigation, even where the generic has little reason to be confident regarding its prospects on the merits. *See* Smith et al., *Generic Drugmakers Will Challenge Patents Even When They Have a 97% Chance of Losing: The FTC Report that K-Dur Ignored*, CPI Antitrust Chronicle September 1 (2012).

In the paradigm litigation settlement, the party accused of wrongdoing pays the aggrieved party some fraction of the potential damages exposure as the central exchange in the settlement of the dispute. The accused party here, however, the ANDA filer, has no damages exposure, and the potential for a tremendous reward. *See* Emily Michiko Morris, *The Myth of Generic Competition Under the Hatch-Waxman Act*, 22 Fordham Intell. Prop. Media & Ent. L.J. 245, 269-73 (2012) ("In effect, the Hatch-Waxman Act actually makes pharmaceutical patents weaker than any other type of patent by making

challenges to pharmaceutical patents easier and more attractive than for any other type of patent."). Under such imbalanced circumstances, sometimes the only way that the parties can "meet in the middle" financially is for the patentee to make some express payment to the infringer. *See* Christopher M. Holman, *Do Reverse Payment Settlements Violate The Antitrust Laws?*, 23 Santa Clara Comp. & High Tech. L.J. 489, 500-502 (2007) ("Holman, *Reverse Payment Settlements*"); *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294, 1310 (11th Cir. 2003) ("Given the asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.").

Appreciating the unique balance of incentives and risks in the Hatch-Waxman litigation context, as well as the widespread aversion to the uncertainty and costs inherent in patent litigation, are among the many reasons that most courts to examine so-called reverse payment settlements have found that these settlements are not inherently anticompetitive and not in violation of antitrust laws. *See, e.g.*, *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003).

B. Congress Has Addressed as It Saw Fit the Antitrust Issue that the FTC Now Presents.

Changes to the balance of incentives in Hatch-Waxman litigation, or in the manner that the validity of issued patents may be challenged by third parties, are matters for Congress, not the courts. Congress has considered the

position of the FTC, and the positions of the many amici in this case, and responded with legislation that Congress deemed appropriate for protecting the public interest in innovative and affordable pharmaceutical products.

Congress first took interest in reverse payment settlements in 2002 when the U.S. Senate unanimously passed the Drug Competition Act of 2001, requiring all settlements between generic and brand-name manufacturers involving agreements over "the manufacture, marketing or sale of the brand name drug . . . [or] of the generic drug" or "the 180-day [exclusivity] period" to be disclosed to both the FTC and the Department of Justice. S. 754, 107th Cong. § 5(a)(2)(as reported by S. Comm. on the Judiciary, June 20, 2002). A version of this bill was incorporated into the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. *See* MMA, Pub. L. No. 108-173, §§ 1111–18, 117 Stat. 2066 (2003). Although the Act ensured that such settlements were brought to the attention of the FTC and DOJ, it conferred no new enforcement authority on either. Rather, the bill "enhance[d] the effectiveness and efficiency of the enforcement of [existing] antitrust laws" "by providing timely notice." S. 754 § 3.

Congress continued to examine the issue, and considered other bills proposing to restrict the ability of parties to enter into reverse payment settlement agreements, but chose not to enact any such laws. For example, in the 109th, 110th, and 111th Congresses, Senator Herb Kohl (together with between four and nine co-sponsors from both parties) introduced the Preserve Access to Affordable Generics Act. S. 369, 111th Cong. (as introduced in Senate, Feb. 3, 2009); S. 316, 110th Cong. (as

introduced in Senate, Jan. 17, 2007); S. 3582, 109th Cong. (as introduced in Senate, June 27, 2006). The proposed bills made it unlawful for a brand-name manufacturer and a generic ANDA filer to enter into any agreement where (i) "an ANDA filer receives anything of value," and (ii) "the ANDA filer agrees not to research, develop, manufacture, market, or sell the ANDA product for any period of time." S. 369 § 3; S. 316 § 3; S. 3582 § 2. None of the proposed bills passed.

Senator Kohl subsequently introduced a revised version of the bill that scaled back the restrictions on reverse settlements. First, payments less than $7,500,000, meant to reimburse the ANDA filer "for reasonable litigation expenses," were not covered by the general prohibition against the ANDA filer receiving anything of value. S. 369, 111th Cong. § 3(d)(2) (as reported by S. Comm. on the Judiciary, Oct. 15, 2009). Second, although reverse payments settlements would be presumed unlawful and anti-competitive, the settling parties could rebut that presumption "if the parties to such agreement demonstrate by clear and convincing evidence that the pro-competitive benefits of the agreement outweigh the anti-competitive effects of the agreement." *Id.* § 3(a)(2). Again, the proposed bill did not pass.[2]

The only action Congress took to address "reverse settlements" was to require the parties to a settlement of a Hatch-Waxman ANDA case to file copies of the settlement

2. Similar bills were considered in the House, and again none passed. For more on the general history of legislative proposals to address "reverse settlements," *see* Gregory Dolin, M.D., *Reverse Settlements as Patent Invalidity Signals*, 24 Harvard J. of L. & Tech. 281, 305-311 (2011).

agreement with the FTC. *See* MMA, Pub. L. No. 108-173, § 1112, 117 Stat. 2066 (2003).

Nothing in the Hatch-Waxman Act or the MMA expanded the scope of antitrust law, prohibited any particular type of agreement, or suggested that any particular type of agreement was presumptively anticompetitive. Indeed, Congress has been presented repeatedly with the substantive and procedural legal rules sought by the FTC in this case and has chosen against them. *See* Gregory Dolin, M.D., *Reverse Settlements as Patent Invalidity Signals*, 24 Harvard J. of L. & Tech. 281, 305-311 (2011) ("Dolin, *Reverse Settlements*"). These are not the actions of a Congress that wished to eliminate reverse payment settlements. To the contrary, these are the actions of a Congress that wished settlements to continue as directed; in a controlled and transparent manner. By pursuing a judicial mandate eliminating reverse payment settlements, the FTC is seeking an end-run around pharmaceutical patent law and Congressional judgment. It is trying to enact, by judicial fiat, the very legislation that Congress explicitly and repeatedly chose *not* to enact.

II. Antitrust Law Is Not the Proper Tool to Examine the Validity of Patents in Settlements.

"[T]he alleged anti-competitive effect of [a reverse payment settlement] agreement [is] the maintenance and issuance of overly broad patents, which themselves are legal monopolies. However, the theory assumes a failure on the part of the Patent and Trademark Office to limit the patents to their proper scope . . . ." *Boston Scientific v. Schneider*, 983 F. Supp. 245, 271 (D. Mass. 1997)

(addressing a settlement of cross claims for infringement and invalidity that included cross-licensing the disputed patents). The FTC's position in this case similarly relies on "a presumption that the PTO is unable to do its job without the assistance of outside parties." *Id.*

The FTC has only recently softened its position against reverse payment settlements, conceding that at least certain kinds of reverse payment arrangements can be pro-competitive. *See Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1062 (11th Cir. 2005) (describing the FTC's position that settlements which do not exceed the cost of litigation are not anti-competitive, as long as such litigation costs are below $2 million). But even those who still advocate for a per se rule against reverse settlements do not—and cannot—suggest that such payments violate the Sherman Act if the patent at issue is valid and infringed.

Instead, there exists among some proponents of the FTC's position the notion that these agreements are designed to preserve patents that should be invalidated. The FTC appears to base this notion, in part, on the false statistic that the generic litigant prevails in 73% of Hatch-Waxman patent cases. *See* 2002 FTC Study; Generic Drug Entry Prior to Patent Expiration; http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf ("FTC 2002 Study"). This statistic, however, references an arbitrary subset of 30 of the 75 actions in which lawsuits were initiated against a first filer. The generic had prevailed in only 22 of the total of 75 actions (about 29.3%). This represents only about 41.5% of the total of the 53 cases resolved. *See* FTC 2002 Study at 14-16.

Moreover, the entire study was debunked several years ago by a subsequent report. The subsequent report

found, for the years immediately following the FTC 2002 Study, that (i) the rate of settlements fell sharply, from 40% to 25%, (ii) the patent holders prevailed in 40% of all the cases brought, and (iii) the generic challenger prevailed in 35%. *See* Gregory Glass, *Why Settle?*, UPDATE, Sept.-Oct. 2005, 17-18 ("[T]his finding suggests that the cases previously being settled were disproportionately ones in which the patents would have been found to be valid and infringed."); *see also* Kent S. Bernard, et al., *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles* 15-4 Fed. Cir. Bar J. 617, 627 (2005-06) ("Bernard, *First Principles*"). Part of the discrepancy between the Glass and FTC reports results from how the FTC arrived at its 73% success rate for generic litigants: the FTC reduced the number of drug products considered, eliminating those with cases still pending, cases that settled, cases in which the generic withdrew its ANDA, and cases in which the same drug patent was litigated more than once. Glass, *Why Settle?* at 19. The self-selection bias resulting from this manipulation of the data set has been resolved in more accurate recent studies, which indicate a lower success rate for the generics than for branded pharmaceutical companies. *See* Adam Greene & D. Dewey Steadman, *Pharmaceuticals: Analyzing Litigation Success Rates*, RBC Capital Markets Corp., 4 (Jan. 15, 2010).

Among other proponents of the FTC's position, it appears that the opposition to settlements in patent cases reflects more general beliefs about the patent system and patent holders that "invalid" or so-called "weak" patents are harming the advancement of technology today. Critics of reverse payment settlements often allege that inferior "innovation" patents, which are (baselessly) assumed to be the subjects of reverse payment settlements, are

preventing consumers from getting access to lower cost medications to which they are entitled. *See* Dolin, *Reverse Settlements* at 318. Not only do these positions rest on false premises, they would not justify changing antitrust law even if they were true. As addressed below, Congress has provided a more focused path to address any such concerns.

A. Congress Has Provided, in the USPTO and Specialty Courts, Appropriate Expert Fora for Determining Patent Validity

The United States Patent and Trademark Office assigns an expert in the field of the claimed invention to examine and approve every patent application before it is issued. Most applications are rejected at least once during prosecution and must be amended to limit the claims to patentable subject matter. If a patent is issued, pursuant to the Patent Act, the patentee is granted "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States." 35 U.S.C. § 154(a)(1).

Once issued, a patent is presumed valid. 35 U.S.C. § 282. This presumption reflects the expertise and competence of the PTO, and the deference due to the decisions of a government agency. *See Microsoft Corp. v. i4i Ltd. Partnership*, 564 U.S. ___, 131 S. Ct. 2238, 2252 (2011) (discussing briefs of respondent and amici).

Nonetheless, anyone (including private parties and government agencies) who believes a substantial question of patentability exists as to a particular patent has two simple and low-cost avenues by which to challenge

that patent—reexamination at the PTO, or an inter partes review. *See* 35 U.S.C. §§ 302, 304, 311, 312 (2012). The Director of the PTO can also order an ex parte reexamination on his own motion whenever he believes that there exists "a substantial new question of patentability." 37 C.F.R. 1.520 (2013). The results of a reexamination or inter-partes review can be appealed to the Board of Patent Appeals and Interferences, a specialized Article I court, and then to the Federal Circuit, a specialized Article III Court created for to address substantive patent law. 35 U.S.C. §§ 306, 319.

Thus Congress has provided avenues of addressing the concern of so-called "weak" or otherwise problematic patents within multiple institutions specifically created for the purpose of evaluating questions of patent validity. These fora are more appropriate for evaluating complex patentability issues than an antitrust lawsuit. *See* Dolin, *Reverse Settlements* at 281, 318-24. Just as Congress has amended the Hatch-Waxman Act to account for concerns about Paragraph IV incentives, "Congress has amended the patent laws to account for concerns about 'bad' patents," and the consequences of their enforcement. *Microsoft Corp.*, 131 S. Ct. at 2252 (citing Optional Inter Partes Reexamination Procedure Act of 1999, 113 Stat. 1501A-567, codified at 35 U.S.C. § 311 et seq.).

The FTC's approach of presuming illegality for certain types of patent litigation settlements assumes—contrary to the express statutory presumption of validity—that the underlying patent is invalid. There can be no cognizable harm to competition in a patent settlement if the patent is valid and infringed, and the settlement does not restrict conduct beyond the scope of the exclusive patent

right. Any attempt to police patent settlements based on suspected patent invalidity (whether or not triggered by the alleged existence of a reverse payment settlement and alleged weakness of the patentee's case) thus inserts a patent validity trial into an antitrust suit. *See* Dolin, *Reverse Settlements* at 284 ("the antitrust approach . . . would transform the traditional economic arguments into patent litigation.") The resulting trial-within-a-trial is an inefficient and ill-suited means to achieve the goal of ensuring that only valid patents are enforced. *Id.* Not only do such lawsuits necessarily conflate competing patent law and antitrust concepts, but they are appealed to regional Circuit Courts, which Congress has found to be disfavored fora for evaluating patent validity. *See* Dolin, *Reverse Settlements* at 284-85.

B. The Standard Applied by the Eleventh Circuit Is the Correct Standard for Integrating Patent Law and Antitrust Law.

If the enforcement of a patent would have excluded a generic product from the market, then there can be no competitive harm and no antitrust liability in a settlement agreement that excludes the generic product from the market to an equal or lesser extent. The first question presented in an antitrust case arising from any settlement, Hatch-Waxman or otherwise, is "what lawful competition has been reduced by the settlement?" That question does not turn on who paid whom or how much was paid. Instead, the answer to that question requires proof that the allegedly excluded generic competition was in fact *lawful* under the patent laws.

That proof, in turn, requires more than the mere suspicion that the generic challenger would have likely prevailed had the patent case been tried to a final judgment. As Judge Posner has explained "No one can be *certain* that he will prevail in a patent suit." *Asahi Glass Co., Ltd. v. Pentech Pharmaceuticals*, 289 F. Supp. 2d 986, 993 (N.D. Ill. 2003). Every settlement, in every area of litigation, is a response to uncertainty on both sides. The only way that an antitrust court could conclude, after the fact, that the generic product would *not* have infringed the patent (without a full-blown patent trial) is if it is clear that the claim of infringement of a valid patent was so objectively baseless that no reasonable patentee could realistically expect success on the merits. Indeed, that is what this Court dictated as the proper standard in *Professional Real Estate Investors, Inc. v. Columbia Pictures, Inc.*, 508 U.S. 49, 60-61 (1993). That same standard is followed in the Eleventh Circuit decision below.[3]

One problem inherent in any alternative standard is the difficulty of determining the chances of success in the underlying patent litigation. Opposing parties in litigation often have different views on their respective chances of success, which explains why they are litigating and did not settle immediately once the dispute arose. Those different assessments can be an obstacle to pro-

3. Of course, under the standard applied by the Eleventh Circuit, the FTC might also have alleged a basis for an antitrust claim if it had alleged that the patent was procured by fraud on the patent office, as in *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177 (1965), or if it had alleged a restraint outside the scope of the patent. *FTC v. Watson Pharma., Inc.*, 627 F.3d 1298, 1312 & n.10 (11th Cir. 2012).

competitive settlement agreements, and that obstacle might be addressed through reverse payments where agreement on time of entry cannot be reached. *See* Bernard, *First Principles* at 630.

Such settlements may enhance consumer welfare, for example, by allowing a cheaper alternative on to the market sooner than the expiration of the patent (which is presumed under the Patent Act to be valid), or sooner than the result of litigation would yield 75%, 50%, or 25% of the time, depending on how parties respectively might discount their chances of success. Clearing the dispute enhances consumer welfare. Consumer welfare is also enhanced by avoiding the result of unnecessarily risking the loss of a patent that is presumed valid and likely (but not certain) to be held valid. Forcing the patent holder to risk such loss will lead to dampened innovation and less than optimal allocation of resources to development new drugs to save or improve people's lives. *See id.* at 631.

By way of example, where the patent holder sees a 75% chance of success, and the generic infringer sees a 51% chance of success, and the parties cannot agree on a date of entry to settle the dispute, the litigation could proceed. *See* Smith, Antitrust Chronicle at 1. In the litigation, both destruction of the patent and incentive for innovation and prevention of any generic entry until the expiration of the patent are arguably "likely" results from various parties' perspectives. Moreover, in either result, the courts might reach the wrong conclusion, as suggested by the notoriously high reversal rate in patent appeals. *See* Holman, *Reverse Payment Settlements* at 559.

There is no doubt that reverse payment settlements have some pro-competitive effects, especially as reverse

settlements challenged by the FTC have involved early generic market entry—thus *guaranteeing* that consumers will pay lower prices before the patent expires. *See, e.g.*, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005). The overall competitive effects of such settlements are by no means "easily ascertained," as required for a presumption of illegality. *See California Dental Association v. FTC*, 526 U.S. 756, 771-78 (1999). This is partly because they inherently depend on complex questions relating to the merits of the underlying patent litigation. Adoption of a standard 180 degrees removed from that applied by the Eleventh Circuit, under which all reverse payment settlements are presumptively illegal, is not what Congress chose in 1984 or in 2003, is not consistent with this Court's precedent, including *PRE* and *California Dental*, and ignores that the competitive effects of reverse payment settlement agreements inherently depend on the underlying patent issues and, like them, are exceedingly difficult to assess.

III. The FTC's Arguments for Judicial Legislation Against Reverse Payment Settlements Ignore the Benefits of the Patent System.

Enforcing valid patents increases consumer welfare by providing the proper incentives for innovation. *See* Bernard, *First Principles* at 618. Nowhere is this contribution more keenly felt than in the pharmaceutical industry. *Id.* at 623.

The sheer cost and risk of new drug discovery and development is immense. An FTC Bureau of Economics staff report in 1999 took note of various estimates that the average cost of launching a successful new prescription drug approximated $350 million in the 1980s and may

have increased substantially since then. *See* Roy Levy, Fed. Trade Comm'n, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change* 175-78 & n.3 (1999) ("*FTC Discussion*"). Another more recent study indicated that, in constant 2000 dollars, costs dramatically increased from $138 million in 1975, to $318 million in 1984, and $802 million in 1997. Joseph A. DiMasi, et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. Health Econ. 151, 167 (2003).

Furthermore, as the FTC report also noted, innovation is not only unusually costly in the pharmaceutical industry, it is also unusually risky. According to the FTC report, for every 5,000-10,000 compounds screened in preclinical testing, only five reach the clinical testing phase, and only one receives FDA approval. *FTC Discussion* at 178. A current report by an industry trade association puts the number at one out of 10,000. *See* Pharmaceutical Research & Manufacturers of America, What Goes Into The Cost of Prescription Drugs? 2, http://www. phrma.org/ files/ Cost_of_Perscription_Drugs.pdf.

Patent protection justifies and supports the enormous investment in research and development required to bring a new product to market by allowing the drug innovator to charge what the market will allow, without being undercut by others who have not had to make the investment in innovation. Indeed, these factors inform the decisions of drug innovators as to which drugs to develop. An antitrust policy that reduced prices today, even by a substantial amount, at the expense of a small annual reduction in the rate at which innovation occurs "would be a calamity." F. Easterbrook, *Ignorance and Antitrust*,

Antitrust, Innovation and Competitiveness at 122 (1992). A standard for assessing the competitive effect of reverse payment settlements that fails to address the impact on innovation would also be a calamity.

Along these lines, a U.S. Department of Commerce study indicates that price controls in Organization for Economic Cooperation and Development (OECD) countries, by reducing the revenues available to pharmaceutical innovators, have led to a reduction of an estimated 10% in the number of new molecular entities approved as new drugs annually, or three to four fewer new drugs per year. *See* Kevin M. Murphy et. al., *The Economic Value of Medical Research*, *in* Measuring the Gains of Medical Research, 41-42. Due to the virtual lack of lower constraint on generic pricing, and the mandatory generic substitution laws and their managed care counterparts, once the patent protection ends (either by patent expiration or by a successful Paragraph IV certification), sales of the brand-name drug effectively end or are reduced to a minor share of the market.

The FTC and amici in this case premise their positions on the public welfare, and the alleged benefit to consumers of earlier access to lower cost medications. This argument completely ignores the basic economic fact, however, that the patent is often all that enables the brand-name company to develop that new drug in the first place. If a settlement prevents or delays the *infringing* entry of a generic to the marketplace, such prevention of infringement of a valid patent has a strong, albeit difficult to measure, *pro-competitive* effect. "The implicit bargain [of the patent system] is that [for society as a whole] the short term loss in static allocative efficiency [caused by

patents] will be more than offset by the gain in dynamic efficiency" resulting from the reward to innovation that patents confer. Tom and Gillman, *U.S. and E.C. Antitrust Approaches to Patent Uncertainty*, 34 Law & Pol'y Int'l Bus. 859, 870 (2003). Early entry of an infringing generic into the marketplace is theft of the innovator's intellectual property. That theft dismantles the function of patents to promote the very innovation that the FTC wants to police.[4]

The belief that consumers suffer a loss from settlements within the scope of the patent ignores that the settlement at issue, like the other settlements challenged by the FTC, involved the surrender of at least some of the patent term. This surrender guarantees consumers an earlier market entry of a generic drug, as opposed to the mere chance of earlier entry contingent on the generic prevailing in litigation. Once again, there is some pro-competitive effect, but it is as difficult to measure as the merits of the underlying patent litigation. More importantly, the belief that consumers suffer a loss from settlements also "ignores the first principle that enforcing valid patents makes a major contribution to consumer welfare by providing the incentive for innovation. We ignore that incentive at our peril." Bernard, *First Principles* at 618.

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4. At least one study suggests that Paragraph IV challenges by generic manufacturers have shortened effective patent lives by at least 1.5 years, and that this held true *regardless* of whether the challenges were successful. *See* Henry G. Grabowski & Margaret Kyle, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 Managerial & Decision Econ. 491, 501 (2007).

CONCLUSION

The Eleventh Circuit decision applies the proper test for evaluating a patent litigation settlement under antitrust law and should be affirmed.

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AMICUS CURIAE BRIEF

RECORD
AND
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FEDERAL TRADE COMMISSION
Petitioner,

v.

ACTAVIS, INC., ET AL.
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF OF ENAVAIL, LLC AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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INTERESTS OF *AMICUS CURIAE*

Amicus curiae Enavail, LLC ("Enavail") is an innovative, Austin-based company that develops new pharmaceutical formulation technologies. Enavail's founders initially developed the patented technology underlying Enavail's business at the University of Texas at Austin, which has licensed that patented technology to Enavail. Enavail's proprietary technology relates generally to new formulations for drugs that provide superior potency as well as enhanced bioavailability and dissolution. In other words, Enavail, like the developer of AndroGel®, develops the formulation technologies that help make the active pharmaceutical ingredients in drugs work better to treat patients.

Petitioner Federal Trade Commission ("FTC") and its *amici curiae* have attacked the pioneering formulation technologies that Enavail and other innovator companies develop, thereby threatening significant harm to Enavail and other innovators. Pejoratively referring to the patents covering these technologies as "secondary patents," and ignoring the statutory presumption of validity afforded these patents, the FTC and its *amicus curiae* seek a broad presumptive rule that effectively would permit the

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[1] Pursuant to Supreme Court Rule 37.6, *amicus curiae* states that (1) no counsel for a party in this case authored this brief, in whole or in part, and (2) no person or entity, other than Enavail or its counsel, made a monetary contribution to the preparation or submission of this brief. Copies of consents from the parties to file this brief have been provided to the Clerk of the Court.

FTC to substitute its judgment for that of the U.S. Patent and Trademark Office ("PTO") and scrutinize these patents under antitrust law using a "'quick look' rule of reason analysis." Adopting this extreme and unwarranted rule would devalue pharmaceutical formulation patents and the innovative technology they protect, and consequently Enavail's patented assets, in which Enavail has significantly invested, would diminish in value. Moreover, Enavail is representative of an entire industry whose patented assets would be devalued by the FTC's proposed rule. As a result, Enavail's interests in this case are substantial.

SUMMARY OF ARGUMENT

This case involves the intersection of antitrust law, patent law and prescription drug law. The Hatch-Waxman Act balances the inherent tensions among these laws, and Congress has generally left this balance intact. The FTC and its *amici curiae* acknowledge this balance but argue that the Court should intercede and permit the FTC to engage in broad antitrust scrutiny of pharmaceutical patents that the PTO duly issues, notwithstanding the strong statutory presumption of validity afforded these patents. In so doing, the FTC and its *amici curiae* mischaracterize the nature of these patents and trivialize the important role these patents serve in protecting and rewarding the significant research and development investments in innovative pharmaceutical technologies. Specifically, the FTC and its *amici curiae* disparage pharmaceutical formulation technology such as the technology underlying the drug at issue in this case, AndroGel®,

as allegedly "secondary" technology protected by "undeserved" patents.

In stark contrast to the unreasonable position of the FTC and its *amici curiae*, numerous examples of successful innovative pharmaceutical products, such as AndroGel®, exist for which the formulation technology has proven critical to the product's clinical and commercial success. As evidenced by consumer demand for these products, particularly in the face of competition from generic products containing the same active ingredient, an innovative formulation is often the ***primary*** technology associated with a successful pharmaceutical treatment. Accordingly, the derision by the FTC and its *amici curiae* of formulation technology as "secondary" and "undeserved" of patent protection is plainly unwarranted, and the Court should reject any proposal by the FTC and its *amici curiae* that would undermine the statutory presumption of validity accorded a lawfully issued patent.

Ignoring the fundamental strength of lawfully issued pharmaceutical formulation patents, the FTC and its *amici curiae* argue that the Court should overturn the Eleventh Circuit's decision and adopt a "'quick look' rule of reason" test for settlements of pharmaceutical patent infringement cases under the Hatch-Waxman Act. Under this proposed test, any settlement of Hatch-Waxman litigation involving a payment from an innovator company to a generic company would be presumptively illegal, thereby subjecting the patent at issue to enhanced antitrust scrutiny, even if the innovator company does not attempt to enforce the patent beyond the scope of its

lawfully obtained claims. This shift to a presumption of illegality would constrain the innovator's patent rights and thus diminish the value of lawfully issued pharmaceutical patents. By diminishing the value of pharmaceutical patents, particularly by engendering an air of suspicion around any patents directed to what the FTC and its *amici curiae* call "secondary" technology, the FTC's proposed "quick look" rule would thwart innovation of pharmaceutical formulation technologies, thereby depriving consumers of new and beneficial therapies.

Indeed, under the FTC's proposed rule, branded pharmaceutical companies would invest less in developing innovative formulations, because the patents that protect these innovations would be subject to enhanced antitrust scrutiny and therefore unquestionably would be weakened. Generic pharmaceutical companies, which rely on the research and development efforts of brand companies when seeking to market generic versions of brand products, in turn would suffer under the FTC's proposed rule. Moreover, weakened pharmaceutical patent protection, and the corresponding reduction in research and development investment in pharmaceutical formulation technology, inevitably would impact innovative formulation technology companies like Enavail as well as the academic research institutions where much pharmaceutical formulation technology originates, such as, for example, the University of Texas at Austin, where Enavail's core technology was first developed.

The FTC's proposed "quick look" rule is not only contrary to the statutory presumption of patent

validity that the Court recently reaffirmed in *Microsoft v. i4i* but also ignores the role of Congress in creating the Hatch-Waxman balance. In each of its past four sessions and its current session, Congress has considered proposed bills seeking to implement a nearly *per se* rule for Hatch-Waxman litigation settlements that is very similar to the FTC's proposed "quick look" rule. Yet Congress has not passed any such bill into law. Even though Congress has passed sweeping changes to both the Patent Act and the Federal Food. Drug and Cosmetic Act ("FDCA") during the same time period, Congress has declined to pass legislation that would accomplish what the FTC seeks through this case. Undeterred, the FTC now asks the Court to grant it additional power to scrutinize the PTO's grant of pharmaceutical patents, notwithstanding the statutory presumption of validity to which these patents are entitled. Such a decision should be left to Congress, and the Court accordingly should affirm the Eleventh Circuit's decision to reject the FTC's requested rule.

ARGUMENT

I. THE CRITICISM OF INNOVATIVE PHARMACEUTICAL FORMULATION TECHNOLOGIES BY THE FTC AND ITS *AMICI CURIAE* IS UNFOUNDED

The FTC and its *amici curiae* start from the premise that pharmaceutical companies such as Respondents have achieved their phenomenal growth over the past decades by obtaining "undeserved" patents related to "secondary" aspects

of the innovative drugs they sell. *See, e.g.*, Pet. Br. at 7; Br. of The Public Patent Foundation as *Amicus Curiae* in Support of Pet. at 8-9; *see also* Br. of Apotex, Inc. as *Amicus Curiae* in Support of Pet. at 8-9. Nothing could be further from the truth. Contrary to the arguments of the FTC and its *amici curiae*, the pharmaceutical industry has experienced unparalleled growth because health care professionals and their patients demand the innovative formulations that the pharmaceutical industry develops. Far from being "undeserved," the patents protecting these innovative formulations reward research and development and ensure future technological advances.

A. The Growth and Success of the Pharmaceutical Industry Owe to the Development of Innovative Formulations

Indeed, the growth and success of the pharmaceutical industry, which the FTC and its *amici curiae* criticize, owe to the development of innovative formulations that benefit consumers. For example, the well-known heartburn medication Prilosec®, which was the best-selling pharmaceutical product in the United States in the late 1990s, is an innovative formulation of the active ingredient omeprazole. *See, e.g.*, B.A. Berkowitz and G. Sachs, *Life cycle of a block buster drug: discovery and development of omeprazole (Prilosec)*, 2 Molecular Interventions 6 (2002). Omeprazole itself was invented in 1979, but the key to its success was the development of a pioneering formulation including an enteric coating to protect the active ingredient.

In 2008, the Court of Appeals for the Federal Circuit affirmed judgments of infringement, validity and enforceability of the patents covering this formulation. *See In re Omeprazole Patent Litig.*, 536 F.3d 1361, at 1373, 1375 (Fed. Cir. 2008) ("Impax argues that it was known in 1979—the year Astra filed its first patent application for omeprazole—that omeprazole could provide a safe and effective treatment. Impax's argument misses the point. . . . The challenge they faced was developing a formulation to deliver omeprazole to the small intestine, a challenge that was made difficult by omeprazole's sensitivity to acidic environments, such as the stomach."). Because of this innovative formulation, Prilosec® gr ·dly exceeded expectations in a crowded field of acid reflux treatments known as proton pump inhibitors. *See* Berkowitz.

Prilosec®, like Androgel®, is a dramatic success story in the high-risk/high-reward pharmaceutical industry, where there are a thousand failures for every drug that successfully enters the clinical study stage. *See, e.g.*, Rosa M. Abrantes, Christopher P. Adams, and Albert Metz, *Pharmaceutical Phases: A Duration Analysis* 5 (FTC Bureau of Economics, Working Paper No. 274, October 2004) ("[A]ccording to the FDA, 1 in 1,000 drugs pass the preclinical stage and are proposed for testing in humans (FDA, 2002), however almost half the R&D expenditures occur in the preclinical stage of development."), *available at* http://www.ftc.gov/be/workpapers/wp274.pdf. Moreover, recent studies indicate that once a 1-in-1000 drug enters the clinic, the success rate is only about 25%, with an average clinical development period of over eight years and a total

cost from preclinical research to approval averaging $802 million. *See id.* at 4, 8; *see also* Congressional Budget Office, *Research and Development in the Pharmaceutical Industry* 19 (October 2006), *available at* http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/76xx/doc7615/10-02-drugr-d.pdf. More recent studies found the clinical success rate to be less than 20% and the cost to develop a single approved drug to be up to $1.8 billion. Joseph A. DiMasi, *Pharmaceutical R&D Performance by Firm Size: Approval Success Rates and Economic Returns*, Am. J. Therapeutics, (published online Jan. 23, 2013), *available at* http://journals.lww.com/americantherapeutics/Abstract/publishahead/Pharmaceutical_R_D_Performance_by_Firm_Size__.99463.aspx; Joseph A. DiMasi and Henry G. Grabowski, *R&D Costs and Returns to New Drug Development: A Review of the Evidence, in The Oxford Handbook of the Economics of the Biopharmaceutical Industry* 21, 23 (Patricia M. Danzon and Sean Nicholson ed., 2012).

Like other successful innovative formulations, AndroGel® is a successful product because health care professionals and patients value the treatment AndroGel® provides. The FTC and its *amici curiae* criticize AndroGel®, however, arguing that its active ingredient, testosterone, has been known for over a century and methods for synthesizing testosterone were developed decades ago.[2] This criticism begs the

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[2] The first testosterone synthesis was published in 1935. John M. Hoberman and Charles E. Yesalis, *The History of Synthetic Testosterone*, 272 Sci. Am. 76 (1995).

question why AndroGel® has attained such success that consumers purchased over $1 billion worth of AndroGel® in 2011 alone, particularly given that numerous generic testosterone products containing the same active ingredient are commercially available. *See* Top 100 Drugs for 2011 by Sales, http://www.drugs.com/stats/top100/2011/sales; *see, e.g.*, Drugs@FDA: FDA Approved Drug Products, Testosterone Cypionate, http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&DrugName=TESTOSTERONE%20CYPIONATE. Quite simply, the unique formulation of AndroGel®, which the FTC downplays as merely containing "certain other ingredients," Pet. Br. at 9, makes it safer and more effective than other treatment options. Christina Wang et al., *Long-Term Testosterone Gel (AndroGel) Treatment Maintains Beneficial Effects on Sexual Function and Mood, Lean and Fat Mass, and Bone Mineral Density in Hypogonadal Men*, 89 J. Clin. Endocrin. & Metabol. 2085 (May 2004) (noting that AndroGel® has fewer side effects, particularly affecting bone density, than other testosterone treatments). Moreover, that the innovative AndroGel® formulation was not developed until the 1990s, despite that synthetic testosterone products had been available for decades, strongly suggests that AndroGel® has satisfied a longstanding need for a safer, more effective treatment where others had failed. *See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 405 (2007) (citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966)); *see also In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1083 (Fed. Cir. 2012) (holding that claims directed to an innovative

formulation of a known drug were nonobvious in light of the fact that the "objective indicia of failure of others and longfelt need are particularly telling").

Notwithstanding the success of pioneering formulations such as AndroGel®, the FTC and its supporting *amici curiae* deride such innovative formulations as "secondary" technology and suggest that the only meritorious pharmaceutical technology is the active ingredient itself. *See, e.g.*, Pet. Br. at 4, 7; Br. of The Public Patent Foundation as *Amicus Curiae* in Support of Pet. at 8-9; Br. of 118 Law, Economics and Business Professors and Am. Antitrust Inst. as *Amicus Curiae* in Support of Pet. at 4. This suggestion ignores the successful and beneficial nature of pharmaceutical formulation technology. As discussed above, for example, the success of AndroGel® owes to its unique formulation, as evidenced by AndroGel®'s phenomenal success in the marketplace competing against numerous generic testosterone products having the same active ingredient, as well as AndroGel®'s satisfaction of a long-felt need for a safer, better treatment of hypogonadism than other therapeutic options.

B. Courts Repeatedly Have Rejected the Suggestion of the FTC and its *Amici Curiae* that Formulation Patents are "Secondary" or "Undeserved"

Moreover, courts repeatedly have rejected the suggestion that patents directed to new formulations of existing active pharmaceutical ingredients are "secondary" or "undeserved." Indeed, recent cases

before the Court of Appeals for the Federal Circuit illustrate the ***primary*** importance of formulation technology and the strength of patents covering this technology. *See, e.g., Pozen Inc. v. Par Pharmaceutical Inc.*, 696 F.3d 1151 (Fed. Cir. 2012) (affirming non-obviousness of patent claims covering formulations of Treximet®, a combination therapy for treating migraines); *In re Cyclobenzaprine Hydrochloride*, 676 F.3d at 1082-84 (reversing district court's finding of obviousness for patent claims covering formulations of the well-known drug cyclobenzaprine hydrochloride); *Unigene Laboratories Inc. v. Apotex Inc.*, 655 F.3d 1352 (Fed. Cir. 2011) (affirming district court's finding of non-obviousness for patent claims covering formulations of calcitonin with enhanced bioavailability); *In re Kao*, 639 F.3d 1057 (Fed. Cir. 2011) (reversing Patent Office Board of Patent Appeals and Interferences holding of obviousness of patent claims covering controlled release formulations of oxymorphone); *In re Omeprazole*, 536 F.3d at 1380-81.

The Federal Circuit's opinion in *In re Cyclobenzaprine Hydrochloride* is particularly illustrative. In reversing the district court's finding of obviousness of the claimed pharmaceutical formulation as not supported by clear and convincing evidence, the Federal Circuit stated, "If we were to affirm the district court's obviousness ruling on the basis of this record, we effectively would announce . . . a categorical rule that it is always obvious to try to target bioequivalence when formulating an extended-release formulation." *In re Cyclobenzaprine Hydrochloride*, 676 F.3d at 1083-84.

Contrary to the posture of the FTC and its supporting *amici curiae*, the Federal Circuit's *Cyclobenzaprine* opinion makes clear that formulation technology should not be relegated to "secondary" status. *Id.* If such technology were merely "secondary," which it is not, it would not take decades of research and hundreds of millions of dollars to develop innovative formulations, and consumers would not choose them over available less expensive generic options having the same active ingredient.

C. The FTC's Proposed Rule Would Undermine the Statutory Presumption of Validity for Formulation Patents

In spite of the wealth of recent case law supporting the strength of pharmaceutical formulation patents, the FTC and its *amici curiae* ask this Court to give the FTC broad authority to review the decisions of the PTO and scrutinize these patents under antitrust law. Such enhanced antitrust scrutiny, which would create a presumption of illegality with respect to settlements of Hatch-Waxman litigations involving payments from patent owners to generic challengers, would undermine the statutory presumption of patent validity. Indeed, as the Court recently reaffirmed, duly issued patent claims are entitled to a statutory presumption of validity, and clear and convincing evidence is required to overcome this presumption. *Microsoft Corp. v. i4i Limited Partnership*, 131 S.Ct. 2238 (2011). In *Microsoft v. i4i*, Microsoft and its

amici curiae attacked this statutory presumption, propounding arguments regarding allegedly "undeserved" patents similar to the arguments that the FTC and its *amici curiae* advance in this case. *Id.* at 2251-52. The *Microsoft* Court rejected those arguments, and the Court likewise should reject them here. *Id.*

Contrary to the arguments of the FTC and its *amici curiae*, the Eleventh Circuit's "scope of the patent" test is consistent with the statutory presumption of validity to which every lawfully issued patent is entitled. *F.T.C. v. Watson Pharmaceuticals, Inc.*, 677 F.3d 1298, 1308 (11th Cir. 2012). Upholding the "scope of the patent" test in turn would prevent the FTC from substituting its judgment for that of the PTO and consequently weakening pharmaceutical formulation patent claims, such as those covering AndroGel®. Enavail respectfully requests that the Court reject the unwarranted attack by the FTC and its *amici curiae* against the important technological advances such as those at issue in this case.

II. ADOPTION OF THE FTC'S "'QUICK LOOK' RULE OF REASON" WILL THWART PHARMACEUTICAL FORMULATION INNOVATION

The FTC and its *amici curiae* argue that, because pharmaceutical innovators obtain and enforce formulation patents such as those covering AndroGel®, the Court should adopt a "quick look" standard under which payments from innovator companies to generic companies in connection with

patent litigation settlements would be presumptively illegal. As discussed above, this argument is premised upon the derogation of formulation patents as "secondary" or "undeserved," which is an entirely unsound premise. Moreover, hampering the ability of patent owners to settle expensive, risky patent litigation will harm pharmaceutical innovation by diminishing the value of formulation patents that protect innovation. As discussed below, this harm will thwart a broad range of research and development activities, including those of pharmaceutical companies, innovative formulation development companies such as Enavail, and academic research institutions.

A. The Pharmaceutical Industry's Research and Development of Innovative Formulation Technology Will Diminish If Patent Protection Is Weakened

The pharmaceutical industry relies on patent protection to obtain positive returns on investments of hundreds of millions or even billions of dollars in research and development expenditures. *See* Henry G. Grabowski and Jeffrey L. Moe, *Impact of Economic, Regulatory and Patent Policies on Innovation in Cancer Chemoprevention* 13 (Duke Univ. Econ. Working Paper Series, Nov. 2007) ("several studies have found that the pharmaceutical industry places the highest importance on strong patent protection to support research and development activities"), *available at* http://econ.duke.edu/research/working-paper-series#2000-2004; Meir Perez Pugatch, David Torstensson,

& Rachel Chu, *Taking Stock: How Global Biotechnology Benefits from Intellectual Property Rights* 5, Pugatch Consilium (June 2012), at 5 (report commissioned by the Biotechnology Industry Organization summarizing a meta-analysis of research on the effects of patents on biopharmaceutical innovation and finding "IPRs [intellectual property rights], especially patents, are actively facilitating and contributing to upstream and downstream biotechnology activities"), *available at* http://www.bio.org/articles/taking-stock-how-global-biotechnology-benefits-intellectual-property-rights. Absent strong patent protection, innovator pharmaceutical companies simply will not invest in critical formulation technology such as the technology underlying AndroGel®. *See* Grabowski & Moe, at 26 ("Early patent challenges with uncertain outcomes also have a chilling effect on the development of new indications and formulations."). Without question, the value of pharmaceutical formulation patent claims, and hence the incentive for the pharmaceutical industry to continue its research and development efforts, would diminish substantially if the statutory presumption of validity afforded to these patents is undermined by the "quick look" rule proposed by the FTC and its *amici curiae*. *See id.*

As discussed above, such weakening of formulation patent claims invariably would disincentivize brand pharmaceutical companies from investing in the research and development of innovative pharmaceutical formulations, thereby harming consumers by depriving them of new therapeutic options. *See id.* Moreover,

disincentivizing brand pharmaceutical companies from developing and marketing new pharmaceutical formulations would deprive consumers of additional potential generic options, as generic companies rely on the research and development efforts of brand companies when seeking to market generic versions of brand drugs. *See, e.g.*, 21 U.S.C. 355(j)(2)(A) (setting forth requirements for applicants seeking to market generic versions of approved brand drugs). Accordingly, and ironically, the very consumer interests that the FTC and its *amici curiae* purport to espouse would in fact suffer from the "quick look" rule, as the pharmaceutical industry's development of new and innovative formulations would be disincentivized.

B. Companies Such as Enavail and the Innovative Formulation Technology They Develop Will Be Jeopardized by the "Quick Look" Rule

Innovative formulation technology companies such as Enavail likewise would be jeopardized under the "'quick look' rule of reason" that the FTC and its *amici curiae* seek. Particularly for start-up formulation technology companies like Enavail, which typically do not have the organizational infrastructure and capital necessary to carry out clinical trials or market innovative new therapies themselves, and which typically do not own many fixed assets or hold substantial brand equity, the patents protecting their innovative formulations are even more important than they are for a branded pharmaceutical company. Often, in fact, these patents are the primary valuable assets of

formulation technology companies. *See, e.g.*, Stuart J.H. Graham et al., *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24 Berkeley Tech. L.J. 1255, 1305 (2009) ("A reason why patents are so important in the biotechnology industry in particular is that, when one makes a biotech investment, fundamentally one is making an IP investment. Consequentially, the early-stage venture investors dig very deeply into the validity of that IP."). Accordingly, adopting the "quick look" rule, which would diminish the value of pharmaceutical formulation patents, would significantly harm these innovative companies.

Moreover, because formulation development companies typically license their innovative technology to pharmaceutical companies for use in marketed drugs, the deleterious effect of the "quick look" test on the pharmaceutical industry would invariably harm formulation development companies as well. *See, e.g., Elan Drug Technologies Wins Award*, Drug Discovery & Development, Feb. 24, 2011, http://www.dddmag.com/news/2011/02/elan-drug-technologies-wins-award (noting that Elan Drug Technologies' innovative formulations technologies "have been incorporated in over 35 products which have been commercialised in over 100 countries worldwide" through partnerships with branded pharmaceutical companies); Chris V. Nicholson, *Alkermes to Merge With Irish Drug Business*, N.Y. Times, May 9, 2011, http://dealbook.nytimes.com/ 2011/05/09/alkermes-to-merge-with-irish-drug-business (reporting the purchase of Elan Drug Technologies, a company

focused on drug delivery technologies, for $960 million). Opportunities for formulation development companies to market their innovative technologies to pharmaceutical companies would evaporate. Without these opportunities, pharmaceutical innovation would decline and consumers would be deprived of additional therapeutic options, such as, for example, innovative formulations that improve the bioavailability, potency, and toxicology profile of drug treatments. *See* Grabowski & Moe, at 25-26 ("It is worth noting that many important drug products such as the first AIDS therapy, AZT (Zidovudine), relied on formulation or method of use patents because their product patents had already expired.").

For instance, Enavail has developed formulation technologies that improve the potency and bioavailability of drugs such as cyclosporin A and danazol. *See* Enavail Technology, *available at* http://www.enavail.com/technology.html. Both branded and generic manufacturers market these drugs, but the original formulations have problems with their potency and bioavailability. *Id.* Enavail's innovative, patented formulation technology overcomes the shortcomings of the original formulations. *Id.* As discussed above, however, adoption of the "quick look" rule would inevitably harm the value of Enavail's patents and disincentivize companies such as Enavail from developing innovative formulations for consumers.

C. Treating Formulation Patents as "Secondary" Will Significantly Reduce Academic Research

Academic research also will suffer if the "'quick look' rule of reason" that the FTC and its *amici curiae* propose is adopted. Indeed, much academic research in fields such as pharmaceutics, pharmacology and medicinal chemistry is funded by the pharmaceutical industry, and many marketed pharmaceutical products are developed in university laboratories and licensed to pharmaceutical companies. For example, a scientist at Northwestern University developed and patented the blockbuster anti-seizure drug Lyrica®. As a result, Northwestern University was able to sell its royalty rights in Lyrica® for $700 million to be reinvested in the university. *See* Matthew Keenan, *Royalty Pharma Buys Lyrica Rights From Northwestern*, Bloomberg, Dec. 18, 2007, http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aNAeicA8ZdB8.

Academic institutions invest significantly in patenting pharmaceutical formulation technologies and are often co-plaintiffs in Hatch-Waxman litigations. *See, e.g., Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 689 F.3d 1368 (Fed. Cir. 2012) (licensor Princeton University named co-plaintiff); *Pfizer Inc. v. Teva Pharmaceuticals U.S.A., Inc.*, 882 F. Supp. 2d 643 (D. Del. 2012) (licensor Northwestern University named co-plaintiff). Moreover, the patented technology underlying the business of innovative technology companies like Enavail often is developed at universities and subsequently licensed. *See* Pugatch et al., at 36-37.

Devaluing pharmaceutical formulation patents by adopting the FTC's proposed "quick look" rule invariably would dissuade pharmaceutical companies and formulation development companies from licensing patented formulation technology from universities. Accordingly, just as the FTC's proposed "quick look" rule would significantly harm pharmaceutical companies and formulation development companies, so would it harm academic research into innovative formulation technologies.

III. CONGRESS COULD HAVE ADDRESSED HATCH-WAXMAN LITIGATION SETTLEMENTS WHEN IT RECENTLY ENACTED SWEEPING CHANGES TO THE PATENT ACT AND THE FDCA, BUT CONGRESS DID NOT DO SO

Nearly every year since 2006 Congress considered but did not pass legislation proposing a rule for Hatch-Waxman litigation settlements nearly identical to the rule that the FTC and its *amici curiae* have proposed. *See* H.R. 3995, 112th Cong. (2012); S. 27, 112th Cong. (2011); S. 3677, 111th Cong. § 746 (2010); S. 369, 111th Cong. (2009); H.R. 3962, 111th Cong. § 2573 (2009); H.R. 1706, 111th Cong. (2009); S. 316, 110th Cong. (2007); H.R. 1902, 110th Cong. (2007); H.R. 1432, 110th Cong. (2007); S. 3582, 109th Cong. (2006). In each of those years, Senator Herbert Kohl (D-WI) and others attempted to convince Congress to pass the Preserve Access to Affordable Generics Act ("PAAGA"). The PAAGA would have made it illegal for a branded pharmaceutical company to settle a patent

infringement claim in Hatch-Waxman litigation by transferring anything of value to a generic company, unless the FTC authorized the transfer to further competition and benefit consumers. In each of those years, the proposed legislation failed to pass.

Congress did not sit idle, however, during that time period. Rather, Congress passed the most sweeping changes to both the Patent Act and the FDCA in decades. Enacted in September 2011, the America Invents Act, Pub. L. No. 112-29, 125 Stat 284 (2011), is the most significant change to U.S. patent law in over half a century. *See* Press Release, The White House, *President Obama Signs America Invents Act, Overhauling the Patent System to Stimulate Economic Growth, and Announces New Steps to Help Entrepreneurs Create Jobs* (Sept. 16, 2011), *available at* http://www.whitehouse.gov/the-press-office/2011/09/16/president-obama-signs-america-invents-act-overhauling-patent-system-stim ("the *America Invents Act* represents the most significant reform of the Patent Act since 1952"). Few areas of the Patent Act were left untouched by the America Invents Act, from the first-to-invent system that has been a hallmark of U.S. patent law since its inception to the new post-grant trial system and nearly everything in between. *Id.* (summarizing changes to Patent Act).

In 2009, Congress passed the Biologics Price Competition and Innovation Act ("BPCIA"), Pub. L. No. 111-148, § 7002, 124 Stat 119, 804-21 (2010), creating a pathway analogous to the Hatch-Waxman framework to allow generic manufacturers to enter the biologics market. Like the America Invents Act,

the BPCIA implements sweeping changes to the FDCA to provide a regulatory pathway for "biosimilars," which are to biologics what generics are to pharmaceuticals. The BPCIA provides a complex framework for patent litigation between a holder of a Biologics License Application, the biologics equivalent of a New Drug Application, and a manufacturer of a proposed biosimilar. Nowhere in the specific instructions for its complicated patent litigation scheme, however, does the BPCIA address payments from innovators to biosimilar challengers in connection with patent litigation settlements, despite the co-pendency of the PAAGA during the time Congress debated the BPCIA.

Despite this fervor of changes to the Patent Act and the FDCA, and despite the FTC's urging, Congress did not address the PAAGA and instead left in place the "scope of the patent" test as the *status quo*.[3] Just over three weeks ago, Senator Amy Klobuchar (D-MN) once again introduced the PAAGA for Congress to consider. S. 214, 113th Cong. (introduced Feb. 4, 2013). As this Court stated in *Microsoft*, any "recalibration" of the applicable

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[3] Congress also enacted numerous changes to the Hatch-Waxman statutory scheme when it passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"). *See* Pub. L. No. 108-173, §§ 1111-1118, 117 Stat. 2066 (2003) (codified at 21 U.S.C. § 355). In passing the MMA, however, Congress did not adopt the FTC's proposed presumption of illegality with respect to Hatch-Waxman litigation settlements involving payments from innovators to generic challengers. *See id.*

standard should remain in Congress's hands. *Microsoft*, 131 S. Ct. at 2252.

CONCLUSION

For at least the foregoing reasons, the Court should affirm the judgment of the Court of Appeals for the Eleventh Circuit and hold that the "scope of the patent" test is the proper level of antitrust scrutiny for Hatch-Waxman litigation settlements.

Respectfully submitted.

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AMICUS CURIAE BRIEF

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Petitioner,

v.

ACTAVIS, INC. ET AL.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF OF GENERIC MANUFACTURERS UPSHER-SMITH LABORATORIES, INC.; TEVA PHARMACEUTICALS USA, INC.; RANBAXY PHARMACEUTICALS, INC.; MYLAN PHARMACEUTICALS INC.; AND IMPAX LABORATORIES, INC. AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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Pursuant to this Court's Rule 37.2, *Amici Curiae* respectfully file this brief in support of Respondents.[1]

INTEREST OF AMICI CURIAE

Amici Upsher-Smith Laboratories, Inc. ("Upsher-Smith"), Teva Pharmaceuticals USA, Inc. ("Teva"), Ranbaxy Pharmaceuticals, Inc. ("Ranbaxy"), Mylan Pharmaceuticals Inc. ("Mylan"), and Impax Laboratories, Inc. ("Impax") (collectively "Generic Manufacturers") are among the largest generic pharmaceutical companies in the world, with customers throughout the United States and over one hundred countries. Over the past two decades, *Amici* have engaged in hundreds of patent challenges under the Hatch-Waxman Act. Through those challenges, *Amici* and other generic manufacturers have brought numerous affordable generic drugs to market years prior to the expiry of branded companies' patents and saved consumers over $1 trillion, including through litigation settlements. *Amici* therefore have a strong interest in preserving the conditions that enable them to bring such patent challenges, including the flexibility to settle litigation when warranted.

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[1] The parties have consented to the filing of this brief, and their letters of consent are either already on file with the Court or are enclosed for filing with this brief. In accordance with Rule 37.6, *Amici* state that no counsel for any party has authored this brief in whole or in part, and no person or entity, other than the *Amici*, has contributed monetarily to the preparation or submission of this brief.

INTRODUCTION

Amici Generic Manufacturers file this brief to address an issue ignored by the Federal Trade Commission and their *amici*—that the number of patent challenges brought by generic pharmaceutical companies under the Hatch-Waxman Act is directly tied to the generic companies' ability to effectively and efficiently litigate and settle patent litigation arising from such challenges when necessary. Patent challenges are the lifeblood of generic competition, and the only avenue through which generic pharmaceutical products may be brought to market prior to expiration of patents on branded pharmaceuticals. However, FTC's proposed rule would essentially render *per se* anticompetitive any settlement involving consideration from the patent holder to the patent challenger, even though *every* patent settlement involves such consideration. As a result, FTC's proposed rule would all but eliminate monetary consideration—as well as most non-monetary forms of consideration—as an element of settlement for Hatch-Waxman patent cases and thereby make many such settlements difficult, if not impossible, to achieve.

Such a rule would decrease the overall number of patent challenges and thus would itself be anticompetitive. As leading commentators and courts that have addressed this issue have consistently recognized, monetary consideration is often necessary to achieve any settlement for a host of reasons, not least of which is the simple economic reality that patent holders and patent challengers place different values on early entry. Because the value of each day of early entry will cost the patent

holder more (at branded prices) than the patent challenger will benefit (at generic prices), there often is not an entry date that will satisfy both parties. The value of a dollar, on the other hand, is the same to both parties, meaning monetary consideration can bridge the gap and make settlement possible (as happens in ordinary patent litigation and ordinary settlement agreements every day). Removing this critical tool for reaching settlement will mean many cases will not settle that otherwise would.

The resulting impact on competition will be twofold. First, the patent challenger will inevitably *lose* some of the cases, resulting in no entry until patent expiry, whereas a settlement would have resulted in early generic competition to the benefit of consumers. Second, and perhaps most important, the cost of bringing patent challenges in the first place will increase, as generic manufacturers will have to assume that settlement will not be possible (or will be more expensive to achieve). Because resources are finite, generic manufacturers will inevitably bring fewer patent challenges, meaning there will be fewer total opportunities for cheaper generic drugs to enter the marketplace. This is no mere speculation: It is well-documented that at a time when certain courts appeared to view Hatch-Waxman settlements with monetary consideration as unlawful there were fewer overall patent challenges.

FTC's proposed rule would thus *harm* competition. And it would do so simply to eliminate a practice—the exchange of consideration—that is present not only in every patent settlement, but in every settlement of litigation (and every contract). FTC provides no basis to radically rewrite the

antitrust laws in such a manner, and there is none. The Court should reject FTC's approach, which would stifle the development and commercialization of generic pharmaceuticals.

BACKGROUND

The Hatch-Waxman Act sought to lower the cost of prescription medication by fostering the development of generic drugs, and it has been wildly successful. *See, e.g.*, *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997); *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991). Before the Act's passage in 1984, virtually no modern drugs had generic equivalents, and generics filled less than 19 percent of all prescriptions. *See, e.g.*, Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 New Eng. J. Med. 1993, 1993 (2007). Today, some 200 companies market generic drugs in the United States, generic drugs make up nearly 80 percent of all prescriptions, and the widespread availability of generic drugs has saved consumers approximately $1.07 trillion over the last decade alone. *See* Generic Pharm. Ass'n, *Generic Drug Savings in the U.S.* 1-2 (2012), *available at* http://www.gphaonline.org/media//cms/IMSStudyAug2012WEB.pdf (last visited Feb. 27, 2013). Indeed, in 2011, the last year for which data is available, "savings from generics increased 22 percent over the prior year, marking the largest year-over-year increase since 1998, and 10 percentage points higher than the 10-year average." *Id.* at 2.

The Hatch-Waxman Act achieved its goals by reducing the costs to generic pharmaceutical manufacturers of developing generic drugs and bringing those drugs to market. *See generally*

PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2574 (2011). In particular, a generic manufacturer may rely on studies previously conducted by the branded manufacturer and file an Abbreviated New Drug Application ("ANDA") showing that its generic drug is "bioequivalent" to its branded counterpart. *See* 21 U.S.C. § 355(j). A generic manufacturer can also challenge a patent covering a branded drug without making any infringing sales (and thus risking incurring significant monetary damages if its challenge is unsuccessful). To do so, a generic manufacturer simply files an ANDA with a "Paragraph IV" certification—a certification challenging the patent as invalid, unenforceable, or not infringed by the generic drug. *See id.* § 355(j)(2)(A)(vii)(IV). Unless a generic manufacturer files a Paragraph IV patent challenge, the generic product cannot be marketed until all patents claiming the branded drug expire. The filing of a Paragraph IV certification is a technical act of patent infringement, *see* 35 U.S.C. § 271(e)(2), which allows the branded manufacturer to sue immediately for patent infringement rather than waiting until the generic company introduces its generic drug into the market.

In the ensuing litigation, a generic company can obtain a judicial determination regarding patent validity and infringement *before* undertaking the risk of producing and selling a potentially infringing competing drug. As long as the generic company waits for a ruling, including on appeal, before coming to market, it will be liable for few (if any) damages if it loses the patent case, because it will not have made any infringing sales. *See* 35 U.S.C. § 271(e)(4)(C). On the other hand, the branded

manufacturer stands to lose a great deal in the litigation: if the generic company's challenge to the patent is successful, the generic company can enter the market immediately and the branded manufacturer will lose its patent protection forever. The Hatch-Waxman Act thus "alter[ed] the litigation risks of patent lawsuits," putting the Hatch-Waxman patent defendant in the shoes traditionally worn by a plaintiff, and the Hatch-Waxman plaintiff in the shoes traditionally worn by a defendant. *In re Ciprofloxacin Hydrochloride Antitrust Litig.* ("*Cipro I*"), 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003); *see also In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 206-07 (2d Cir. 2006); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1074 (11th Cir. 2005).

This case illustrates the Hatch-Waxman Act operating effectively. Respondent Solvay Pharmaceuticals, Inc. ("Solvay") held a patent covering AndroGel. Pet. Cert. App. 10a. Respondents Watson Pharmaceuticals, Inc. ("Watson") and Paddock Laboratories, Inc. ("Paddock") wanted to sell a generic version of Solvay's AndroGel, so they filed ANDAs with Paragraph IV certifications as to Solvay's patent covering the drug, and Solvay sued both for infringement. *Id.* at 10a-11a. While summary judgment motions were pending in the infringement case, the parties settled their dispute, as parties in all types of litigation routinely do. *Id.* at 12a. Under the terms of the settlement agreement, which included consideration flowing to all parties involved, Watson and Paddock received a license to launch their generic drugs in 2015, fully *five years* before the expiration of Solvay's patent in 2020. *Id.*

SUMMARY OF ARGUMENT

This case presents a straightforward question: can a patent challenger enter into an agreement settling litigation against a patent holder (as litigants do every day), or must it—on threat of treble antitrust damages—litigate the case to the bitter end? Under the rule FTC proposes here, if a patent challenger receives anything of value in that settlement—what FTC pejoratively calls a "reverse" or "exclusion" payment—the settlement would be presumptively unlawful under the antitrust laws, even if the patent challenger received a license to market the patented technology before the expiration of the patent. This is so, according to FTC, because such consideration would be a *quid pro quo* for delayed market entry. But FTC offers a false premise.

As an initial matter, there is simply nothing unusual or untoward about a putative plaintiff providing consideration to a putative defendant as part of a litigation settlement. "*[A]ny* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement." *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J., sitting by designation) (emphasis in original). That point applies with special force in the Hatch-Waxman context, in which the traditional stakes and incentives of litigation are altered and a branded manufacturer (although nominally the plaintiff), seeks to defend a challenge to its patent by a generic manufacturer (nominally the defendant), and may be unwilling to "roll the dice" in litigation. *See, e.g.*,

Tamoxifen, 466 F.3d at 210. There is, thus, nothing "reverse" about a so-called "reverse payment."

Nor is there anything "exclusionary" about such a payment. In arguing to the contrary, FTC simply—and simplistically—assumes that consideration provided to a generic patent challenger must be a *quid pro quo* for delayed market entry and that, absent such consideration, the patent litigants would reach a "better" settlement. FTC's argument, however, is not only legally irrelevant, *see Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 415-16 (2004), but ignores the real-world complexities that even its own *amici* acknowledge make settlements—which greatly benefit consumers—impossible without monetary or similar consideration passing to the patent challenger.

Moreover, the rule FTC proposes would in fact severely harm consumers by reducing the total number of patent challenges in the first place. Every patent challenge—and *Amici* Generic Manufacturers have brought over 100 patent challenges in recent years—brings with it the imminent threat of patent litigation, which is expensive, time-consuming, and inherently uncertain. Indeed, collectively, *Amici* Generic Manufacturers have invested approximately half a billion dollars in patent litigation over the past few years. Settlement, thus, is a key tool for managing the expense and risk of patent litigation. FTC's proposed rule, by effectively banning Hatch-Waxman settlements that involve monetary consideration—and most forms of non-monetary consideration—would render settlement in many Hatch-Waxman patent cases impossible, and in

others inordinately expensive and risky. Yet, such settlements bring lower-cost generic drugs to market *prior to the expiration of the patents* covering such drugs, engendering competition that would not otherwise be possible. Under FTC's desired regime, generic companies would face the dilemma of being locked into protracted patent litigation or trading that litigation for antitrust litigation (and the specter of treble damages). For generic drug companies, which have finite resources with which to develop drugs and mount patent challenges, the upshot would be fewer challenges and decreased drug competition—all to the detriment of consumers.

ARGUMENT

I. There Is Nothing "Reverse" Or "Exclusionary" About So-Called "Reverse," "Exclusion" Payments.

FTC asserts that the settlements in this case violate the antitrust laws for one reason and one reason alone: the settlements (allegedly) contain monetary payments from the patent holder to the patent challengers. But FTC ignores the basic fact that in *every* settlement agreement, as in every contract, each side provides consideration to the other.

In the typical patent case, outside the context of Hatch-Waxman, litigation is not commenced until the alleged infringer (the patent challenger) enters the market and uses, makes, or sells an infringing product. It is only *after* infringing activity has occurred that the infringer can challenge the patent. The patent holder sues the alleged infringer and seeks damages—its lost profits, which may far exceed the alleged infringer's infringing sales—while

the alleged infringer challenges the validity, enforceability, or applicability of the patent. In such a case, the patent holder runs the risk of losing its patent, but the alleged infringer risks incurring significant, and potentially crippling, monetary damages. The companies often will settle to eliminate their respective litigation risks. To avoid its risk, the alleged infringer will typically pay some amount to the patent holder in exchange for ending the litigation. The compensation paid, however, will necessarily be less—and potentially significantly less—than the full quantum of damages sought by the patent holder. The patent holder accepts this smaller amount—and thus grants consideration to the alleged infringer—in exchange for eliminating its risk of losing its valuable patent.

As one report summarized this dynamic: "In this case, the patent holder pays the infringer to settle the lawsuit by accepting lower damages—[although] this payment is obscured by the fact that some cash flows from the infringer to the patent holder." Bret Dickey, Jonathan Orszag, & Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 Annals of Health L. 367, 389 (2010). And where, as is often the case, the alleged infringer does not pay all of its profits on its allegedly infringing sales to the patent holder as damages, the "payment" to the infringer is magnified. *See Cipro I*, 261 F. Supp. 2d at 252 (noting this "implicit consideration" flows to a patent challenger that retains some profit from its infringing sales). Thus, "even in the traditional context, implicit consideration flows from the patent holder to the alleged infringer." *Id.*; *see also Schering-Plough*, 402 F.3d at 1074; Mark G.

Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 Antitrust L.J. 1033, 1046-48 (2004).

Hatch-Waxman patent litigation differs from traditional patent litigation in an important respect (which is completely ignored by FTC). The Hatch-Waxman Act permits a generic manufacturer challenging a patent to commit an act of infringement by simply filing an ANDA with a Paragraph IV certification, before it makes any infringing sales or engages in any other activity that would give rise to compensatory damages. *See* 35 U.S.C. §§ 271(e)(2), 271(e)(4)(C). As a result, Hatch-Waxman patent litigation commences "*before* the filer has spent substantial sums on the manufacturing, marketing, or distribution of the potentially infringing drug," and *before* it has made potentially infringing sales that could subject it to substantial damages. *See Tamoxifen*, 466 F.3d at 206 (emphasis in original); *Cipro I*, 261 F. Supp. 2d at 252. The patent challenger still faces risk—notably, the expense of a drawn-out litigation—but it does not face the threat of substantial money damages. By contrast, the patent holder has the exact same risk it would have in traditional patent litigation—the threat of losing its valuable patent. *See Tamoxifen*, 466 F.3d at 206-07; *Schering-Plough*, 402 F.3d at 1074; *Cipro I*, 261 F. Supp. 2d at 252.

As compared to the traditional patent case, then, the patent challenger in the Hatch-Waxman context faces comparatively less risk and the patent holder faces the same risk. Indeed, the redistributed risks in Hatch-Waxman patent litigation make the patent holder (the branded company) more like the

defendant in a traditional case and the patent challenger (the generic company) more like the plaintiff. For this reason, FTC's attempt to discount Judge Posner's reasoning in *Asahi Glass*, *see* Pet. Br. 30, falls flat, as it fails to understand, or even acknowledge, the economics driving these cases. The patent challenger, although nominally the defendant, has "the whip hand":

> "Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude. Because of the Hatch-Waxman scheme, the generic challengers gain considerable leverage in patent litigation: the exposure to liability amounts to litigation costs, but pales in comparison to the immense volume of generic sales and profits."

Tamoxifen, 466 F.3d at 210 (quoting *Schering-Plough*, 402 F.3d at 1074 (brackets omitted)); *see also In re Ciprofloxacin Hydrochloride Antitrust Litig.* ("*Cipro Fed. Cir.*"), 544 F.3d 1323, 1333 & n.11 (Fed. Cir. 2008) (similar). In light of this reality, "[g]iven the asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement." *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1310 (11th Cir. 2003).[2]

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[2] Only if the generic challenger were to launch its product at-risk—that is, before definitive resolution of the infringement case at the trial and appellate levels—would the litigation risks revert to those of the traditional patent litigation. In that situation (and only in that situation), the generic patent challenger subjects itself to the possibility of infringement

There is thus nothing "extraordinary" or "distinguishing" about consideration flowing to the patent challenger in Hatch-Waxman patent settlements, as FTC claims. *See* Pet. Br. 30. As many courts have observed, net monetary consideration flowing from the patent holder to the patent challenger is "'a natural by-product of the Hatch-Waxman process.'" *Schering-Plough*, 402 F.3d at 1074 (quoting *Cipro I*, 261 F. Supp. 2d at 251). And, contrary to FTC's argument, *see* Pet. Br. 50, such settlements are not unique to the Hatch-Waxman context, but can be seen in other contexts where the relative risks of litigation are redistributed. *See, e.g.*, *Metro-Goldwyn Mayer, Inc. v. 007 Safety Prods., Inc.*, 183 F.3d 10, 13, 17 (1st

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damages. *Cipro I*, 261 F. Supp. 2d at 204. Such damages can be substantial, and even crippling, for the generic company. Indeed, *Amicus* Teva is facing up to $2.1 billion in damages resulting from its at-risk launch of a generic form of the heartburn drug Protonix. *See* Peter Loftus, *Teva Faces Possible Damages From Selling Generic Protonix*, Wall St. J. Online, Feb. 13, 2013, http://online.wsj.com/article/SB10001424127887324162304578302550657347058.html. And Apotex, following an at-risk launch of its generic form of Plavix that lasted only *28 days* was found liable to the branded company for over $442 million in damages. *See id.*; *see also Sanofi-Synthelabo v. Apotex Inc.*, 492 F. Supp. 2d 353, 357-58 (S.D.N.Y. 2007), *aff'd*, 550 F.3d 1075 (Fed. Cir. 2008). Moreover, generic companies, even if ultimately successful in their infringement litigation, must nonetheless book significant up-front litigation reserves to protect against a potential loss. It is thus unsurprising that at-risk launches are uncommon. *See* RBC Capital Markets, *Pharmaceuticals: Analyzing Litigation Success Rates* 7 (Jan. 15, 2010), *available at* http://amlawdaily.typepad.com/pharmareport.pdf.

Cir. 1999) (enforcing trademark settlement with payment to alleged infringer); *In Time Prods., Ltd. v. Toy Biz, Inc.*, 38 F.3d 660, 662, 666-67 (2d Cir. 1994) (enforcing copyright and trade dress settlement with payment to alleged infringer).

Moreover, FTC's proposed rule is especially misguided—and dangerous—because it would apply not only to monetary consideration received by the patent challenger, but to *any* settlement in which a patent challenger receives *anything of value*. *See* Pet. Br. 36 n.7 (stating that "[i]f the economic realities of a settlement coupling an alternative form of consideration with delayed entry paralleled those of the direct payments here ... then a similar [ ] analysis would be justified"). Although FTC does not further explain its position in its brief, its own recent litigation positions in other cases demonstrate the breathtaking reach of its proposed rule. In these cases, FTC has argued that non-monetary consideration should be deemed a "reverse payment" that triggers its proposed rule of presumptive illegality. Specifically, in *In re Effexor Antitrust Litigation*, No. 11-cv-5479 (D.N.J. filed Sept. 22, 2011), and again in *In re Lamictal Direct Purchaser Antitrust Litigation*, No. 12-cv-995 (D.N.J. filed Feb. 17, 2012), FTC argued that Hatch-Waxman patent settlements were presumptively anticompetitive even though no monetary consideration was exchanged, simply because the branded company granted an *exclusive* license to the generic (thus foregoing introduction of agreed not to introduce an "authorized generic" version of the drug at issue in the litigation during the exclusive license period). *See* FTC Br. as *Amicus Curiae* 5-11, *In re Effexor Antitrust Litig.*, No. 11-cv-5479 (D.N.J. filed Aug. 10,

2012), *available at* http://www.ftc.gov/os/2012/08/120810effexoramicusbrief.pdf; FTC Br. as *Amicus Curiae* 6-12, *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 12-cv-995 (D.N.J. filed Oct. 5, 2012), *available at* http://www.ftc.gov/os/2012/10/121005lamictalamicusbrief.pdf.

FTC's proposed rule thus calls into question (and subjects to the threat of antitrust treble damages that may be pursued by government agencies and private litigants alike) *all* forms of consideration, and thus all forms of settlement. And it does so even though, as Judge Posner has observed, "*any* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement." *Asahi Glass*, 289 F. Supp. 2d at 994 (emphasis in original). When one appreciates the fact that the stakes and incentives in Hatch-Waxman patent litigation are redistributed from those of "normal" litigation, it becomes clear that the flow of consideration in a Hatch-Waxman patent settlement is anything but "extraordinary"; rather, it is no different than the flow of consideration in patent settlements that occur every day.

II. By Restricting Settlements, FTC's Proposed Rule Would Reduce Patent Challenges, Decrease Competition, And Harm Consumers.

In the face of this reality, FTC proposes a rule that would re-write antitrust jurisprudence and make Hatch-Waxman settlements involving monetary consideration "presumptively unlawful." In advocating this standard, however, FTC fails to

address what should be a key consideration—that such a rule would render settlements impossible or inordinately expensive and risky and would thus *decrease the number of patent challenges* brought by generic drug manufacturers in the first place, thereby reducing competition in the aggregate to the detriment of consumers.

A. FTC's Rule Would Effectively Prevent Settlements, Thereby Making Patent Litigation More Expensive And Uncertain.

It is of course well-known that litigation in general, and patent litigation in particular, is expensive and time-consuming. *See, e.g., Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558-60 (2007); *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 336 (1971). Indeed, *Amici* Generic Manufacturers have collectively expended a half billion dollars in patent litigation over the past few years. It is equally well-known that litigation is inherently uncertain. *See, e.g., Whitmore v. Arkansas*, 495 U.S. 149, 159-60 (1990) ("It is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case."). As the Eleventh Circuit recognized below, "[r]ational parties settle to cap the cost of litigation and to avoid the chance of losing," because even a party likely to win has no guarantees. Pet. Cert. App. 30a. After all, "[n]o one can be *certain* that he will prevail in a patent suit." *Asahi Glass*, 289 F. Supp. 2d at 993 (emphasis in original). The *Amici* Generic Manufacturers know this well—over the past five years, they have brought over 100 patent challenges, many of which have resulted in

litigation. Of those suits litigated to conclusion, they have collectively lost more than they have won.

Settlement is a key tool for managing the expense and uncertainty of litigation. Having a full range of settlement options permits a party to enter litigation with the knowledge that it can avoid a costly and uncertain trial if the risk or expense outweighs the potential benefit. *See, e.g.*, D. Marie Provine, *Settlement Strategies for Federal District Judges* 1 (Fed. Judicial Ctr. 1986) ("Settlements are desirable, not just because trials are costly ... but because settlements allow parties to 'manage their own disputes' and avoid the uncertainties and limitations of the winner-take-all, imposed decisions that courts make in fully litigated cases."). Indeed, even when a generic manufacturer wins in district court, if it launches a product only to have the Federal Circuit reverse, the generic manufacturer faces crippling financial losses. *See, e.g.*, *supra* note 2. Given the threat of ruinous damages, unless a generic manufacturer wins—and sustains its win on appeal—settlement is the only way to routinely facilitate early entry.[3]

The rule proposed by FTC would limit the ability to settle by effecting a *per se* ban on the use of

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[3] A reversal on appeal of a patent case is no rarity. The Federal Circuit in recent years has reversed or vacated (at least in part) more than 40 percent of its patent appeals. *See U.S. Court of Appeals for the Federal Circuit, Affirmance and Reversal Rates for District Court Patent Infringement Appeals: 2001–2010, available at* http://www.patentlyo.com/files/caseload_patent_infringement_affirmance_and_reversal_rates_2001-2010.pdf.

monetary consideration in the settlement of patent cases. Although FTC argues that its presumption of illegality would be rebuttable, it offers no real explanation of how such a presumption could be rebutted, save for an artificial and arbitrary cap on the amount of consideration tied to litigation costs. *See* Pet. Br. 37-38. And it would leave a generic manufacturer with an untenable option: settle a patent case only to have the settlement litigated and reviewed after the fact, perhaps multiple times (as in the case of *Amicus* Upsher-Smith's settlement with Merck/Schering regarding K-Dur) in litigation against both regulatory authorities *and* the uninhibited private plaintiffs that "account for the overwhelming majority of antitrust litigation in the United States." *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 805 (D.C. Cir. 2001). And all this would come with the sword of antitrust treble damages hanging over the generic manufacturer's head.

Monetary consideration, however, is often a critical element *necessary* to achieve settlement, especially in the Hatch-Waxman context—it is not simply a *quid pro quo* for delay, as FTC presumes. Indeed, it has long been recognized that "[t]here are many circumstances where a reverse payment is necessary to resolve a patent litigation," *e.g.*, Schildkraut, *supra*, at 1034, and that, under many circumstances, the patent holder and patent challenger "cannot eliminate the payment and compromise on an earlier entry date, because no such date is acceptable to both the [patent holder] and the [patent challenger]," Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements That*

Settle Patent Litigation, 49 Antitrust Bull. 655, 677 (2004).

As explained by former Clinton National Economic Counsel members Jonathan Orszag and Laura Tyson, such circumstances include, among others, parties' differing views of the value of litigation, parties' differing views of their likelihood of success in litigation, and cash-strapped generic companies. Dickey, Orszag, & Tyson, *supra*, at 391-95. Indeed, one of FTC's own *amici*, Carl Shapiro, who has consulted for FTC and the Department of Justice and served as a plaintiff-side antitrust expert, agrees: "This is not to say that such payments are necessarily anticompetitive if other factors are brought into the analysis, such as risk aversion and asymmetric information about market conditions, as 'reverse cash payments' may be important in more complex settings for successful settlement." Carl Shapiro, *Antitrust Limits to Patent Settlements*, 43 RAND J. of Econ. 391, 408 (2003); *see also* John P. Bigelow & Robert D. Willig, *"Reverse Payments" in Settlements of Patent Litigation: Schering-Plough, K-Dur, and the FTC (2005), in The Antitrust Revolution: Economics, Competition, and Policy* 248, 273 (5th ed. 2009) ("It also follows from economic logic that the opportunity to employ reverse payments may be necessary for socially beneficial and pro-competitive settlements to be reached, due to such common situations as asymmetric information, excess optimism, and

differential cash needs between the parties to the patent dispute.").[4]

FTC does not even attempt to address these real-world complexities that undermine the faulty premise of its entire argument. Rather, it blindly maintains that consideration passing to a patent challenger must be a *quid pro quo* for delay, and it simply asserts—without support—that branded and generic pharmaceutical manufacturers can just "negotiate a compromise date of entry," "with no money or similar consideration flowing from the brand-name to the generic manufacturer." Pet. Br. 22, 27. On this basis, FTC claims, its proposed rule would not significantly undermine the ability of

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[4] Throughout its brief, FTC relies heavily on the work of its former consultants, current antitrust enforcement authorities, plaintiff-side antitrust expert witnesses, and its own *amici*, and presents the conclusions of that work as undisputed fact. For example, Scott Hemphill, cited extensively by FTC, is Chief of the Antitrust Bureau of the New York State Attorney General's Office and has served as a consultant to the FTC; Carl Shapiro, an *amicus* in this case, has consulted for the FTC and the Department of Justice and serves as a plaintiff-side antitrust expert witness; and Mark Lemley (also an *amicus* in this case), Einer Elhauge, and Alex Krueger are also plaintiff-side antitrust expert witness. Indeed, some of this work has been criticised as "[u]nfortunately" simply "assum[ing] that reverse payments are anticompetitive payments for delay prior to evaluating their cost" and "provid[ing] no empirical analysis of the anticompetitive or procompetitive effects that reverse payments have." *See* Henry N. Butler & Jeffrey Paul Jarosch, *Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation*, 96 Iowa L. Rev. 57, 113 (2010).

parties to settle Hatch-Waxman patent litigation, and would eliminate only anticompetitive conduct.

But FTC's claims ignore the realities of Hatch-Waxman patent litigation—notably, the differing values of time to the patent holder and the patent challenger. For the generic company, an extra day of sales is worth only as much as it would gain at generic prices. For the branded company, however, each lost day of sales is calculated at the higher price of its branded drug. Each extra day will thus cost the branded manufacturer far more than the generic competitor will gain. In such a situation, the branded company's reservation date—"the earliest date at which [it] would be willing to allow the generic to enter the market rather than litigate"—may be later than the latest date at which the generic would agree to enter rather than litigate; there would be a gap between the parties' settlement ranges. *See* Schildkraut, *supra*, at 1043. "[W]ithout a payment from the branded manufacturer to the generic manufacturer, the parties may be unable to reach agreement on a settlement—even if a settlement would lower prescription drug costs by bringing a generic drug to market sooner than would occur if the case were resolved by a court decision." Bret Dickey, Jonathan Orszag, & Robert Willig, *A Preliminary Economic Analysis of the Budgetary Effects of Proposed Restrictions on "Reverse Payment" Settlements* 4 (Aug. 10, 2010); *see also* Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles*, 15 Fed. Cir. B.J. 617, 618-19, 628-31 (2005) (explaining that there are multiple reasons "why a straightforward settlement that simply splits the remaining patent

term may not be available," including "asymmetric time horizons and asymmetric risk profiles or expectations" (emphasis omitted)). In short, absent monetary consideration, "due to the disparity between the brand-name manufacturer's and generic challenger's expected profits, there might not be any date that represents a reasonable litigation compromise for early (pre-patent expiration) entry by the generic challenger." *In re Ciprofloxacin Hydrochloride Antitrust Litig.* ("*Cipro II*"), 363 F. Supp. 2d 514, 536 (E.D.N.Y. 2005).

Monetary consideration may similarly be necessary to bridge the gap between the branded and generic companies' settlement ranges where the generic company is overly optimistic about its probability of success in litigation. *See* Dickey, Orszag, & Tyson, *supra*, at 394-95. In such a case, the "mismatch of beliefs and actual probabilities could create a situation ... where (absent a reverse payment) the generic manufacturer would not be willing to accept any settlement terms the brand-name manufacturer would be willing to offer due to the generic manufacturer's unrealistic belief about its chance of winning. ... [But] a reverse payment can potentially bridge the settlement gap and lead to a settlement that benefits consumers." *Id.*; *see also* Schildkraut, *supra*, at 1063-64.

The same is true in the case of a "cash-strapped generic" that heavily discounts future profits and will only accept settlements that allow for greatly accelerated entry but which would not be acceptable to the branded company. "The latest entry date to which the cash-strapped generic would be willing to agree is earlier than the earliest date to which the

brand-name manufacturer would be willing to agree. As a result, settlement talks would break down." Dickey, Orszag, & Tyson, *supra*, at 393-94. However, "[a] cash payment by the brand-name manufacturer may allow the brand-name and generic manufacturers to bridge the settlement gap ... lead[ing] to a range of settlements that would not have been otherwise feasible." *Id.*

In sum, monetary consideration often will permit a patent holder and a patent challenger to reach a settlement that otherwise could not be reached. As set forth below, this is critical for *enabling* competition and *promoting* consumer welfare.

B. Absent Settlement, Generic Competition Will Often Be Delayed Until Patent Expiration.

To perhaps state the obvious, settlement eliminates the possibility that the patent challenger litigates a case and *loses*, in which case no generic alternative can be marketed until *after the patent expires*. In such cases, settlement gives consumers access to generic drugs earlier than would otherwise be possible. Settlements thus often result in *accelerated* generic entry, and not "delay," as FTC claims. FTC wholly ignores this significant fact.

The examples of tamoxifen, previously the most widely prescribed cancer treatment drug in the world, and blockbuster antibiotic Cipro, are instructive. In the case of tamoxifen, four different generic manufacturers filed ANDAs with Paragraph IV certifications challenging the patent protecting Zeneca's branded tamoxifen drug, and Zeneca sued all four generic challengers. *Tamoxifen*, 466 F.3d at 194-95. Barr Laboratories, the first-filing generic,

and Zeneca reached a settlement that allowed Barr to introduce generic tamoxifen *nine years* prior to the expiry of Zeneca's patent and also included monetary consideration flowing to Barr. *Id.* The three other generic challengers opted to litigate their cases against Zeneca to conclusion, but "[i]n each case, the court ... upheld the validity of Zeneca's tamoxifen patent," and those challengers were prohibited from bringing generic tamoxifen to market until Zeneca's patent expired. *Id.* at 195. But because of—and only because of—Barr's settlement with Zeneca, consumers gained access to lower-cost generic tamoxifen *nine years earlier* than they otherwise would have.

Similarly, with regard to Cipro, Barr Laboratories filed an ANDA with a Paragraph IV certification challenging the patent protecting Bayer's branded Cipro drug, and Bayer sued Barr for infringement. *Cipro Fed. Cir.*, 544 F.3d at 1328. Barr, the first-filing generic, and Bayer subsequently reached a settlement that allowed Barr to market a generic version of Cipro before Bayer's patent expired, and also contained monetary consideration flowing to Barr. *Id.* at 1328-29. Thereafter, four other generic companies filed ANDAs with Paragraph IV certifications, seeking to market generic Cipro prior to patent expiry. *Id.* at 1329. Bayer sued each generic and prevailed in all four cases, thereby preventing any of those companies from selling generic Cipro until its patent expired. *Id.* But again, because of—and only because of—Barr's settlement with Bayer, consumers gained access to lower-cost generic Cipro prior to patent expiration.

At the other end of the spectrum, the case of Plavix (clopidogrel), the world's most highly prescribed blood-thinning medication, is equally instructive. Bristol-Myers held a patent covering Plavix. Apotex, seeking to market a generic version of that drug prior to expiration of the patent, filed an ANDA with a Paragraph IV certification as to that patent, and Bristol-Myers sued it for infringement. The parties reached two separate settlement agreements that would have allowed Apotex to market generic clopidogrel ten-and-a-half months prior to patent expiry. The regulatory authorities, however, rejected those settlements.[5] Apotex then litigated its patent challenge, lost, and was thus enjoined from marketing generic clopidogrel until Bristol-Myers's patent expired. *See Sanofi-Synthelabo v. Apotex Inc.*, 492 F. Supp. 2d 353 (S.D.N.Y. 2007), *aff'd* 550 F.3d 1075 (Fed. Cir. 2008); *see also Sanofi-Synthelabo v. Apotex Inc.*, 488 F. Supp. 2d 317, 323-24 (S.D.N.Y. 2006). According to independent analysts, by rejecting the early-entry settlement, regulatory authorities cost consumers $2.6 billion. *See* Corey Davis et al., *FTC Call for Settlement Ban Is ... Full of Sound and Fury, Signifying Nothing* 7 (Jan. 14, 2010).

FTC ignores this reality and instead attempts to generally discount the benefits of settlement by citing its own 2002 study claiming that generic

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[5] Because of an order entered in previous litigation, the settlement agreements between Apotex and Bristol-Myers were subject to approval by FTC and a consortium of state attorneys general. The state attorneys general rejected both settlements. *See Sanofi-Synthelabo*, 488 F. Supp. 2d at 324.

patent challengers prevail in 73% of cases. *See* Pet. Br. 6. Over and above the inherent unreliability of a litigant relying on its own self-serving study (which is based on non-public data) in litigation, this study and the others on which FTC relies have been roundly criticized by independent scholars.[6] An independent study citing more recent data indicates that the success rate of patent challenges in litigation is in fact far less—48%. RBC Capital Markets, *Pharmaceuticals: Analyzing Litigation Success Rates* 1, 4 (Jan. 15, 2010), *available at* http://amlawdaily.typepad.com/pharmareport.pdf. And yet another study of patent validity decisions over a nine-year period concluded that 73% of challenged pharmaceutical patents were held valid. *See* John R. Allison & Marc A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 217 (1998).

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[6] *See, e.g.*, Dickey, Orszag, & Willig, *supra*, at 3 (opining that FTC's study, on which it bases is claim that Hatch-Waxman settlements cost consumers $3.5 billion annually, is "unreliable"); Corey Davis et al., *FTC Call for Settlement Ban Is ... Full of Sound and Fury, Signifying Nothing* 1-5 (Jan. 14, 2010) (concluding that the FTC study on which FTC bases its claims was "exceedingly flawed," relied on "grossly inaccurate data," improperly "presume[d] patent invalidity across the board," and assumed that settlement is always achievable without monetary payments); *see also* Xiang Yu & Anjan Chatterji, *Why Brand Pharmaceutical Companies Choose To Pay Generics in Settling Patent Disputes: A Systematic Evaluation of the Asymmetric Risks in Litigation*, 10 Nw. J. Tech. & Intell. Prop. 19, 37 (2011) ("[A]lthough the FTC holds the position that consumers suffer a loss up to $3.5 billion per year due to [so-called reverse-payment] settlements, its estimation method has recently been challenged on legal and economic grounds.").

Contrary to FTC's claim, in reality over half, and potentially up to three-quarters, of all patent challenges litigated to conclusion are not successful. In these cases, no generic competition is permitted and consumers are left with only the branded drug at branded drug prices. Consumers would be better off with a settlement that permits early entry, even if that settlement also contains consideration flowing to the patent challenger. FTC's proposed rule would eliminate this competition resulting from settlement, and is thus itself anticompetitive.

C. FTC's Approach Would Result In Fewer Patent Challenges And, Thus, Fewer Generic Drugs For Consumers.

Most fundamentally, by reducing generic companies' ability to settle patent litigation, FTC's proposed rule would cause generic companies to bring fewer patent challenges because, as numerous commentators and courts have recognized, a generic company's incentive to bring Hatch-Waxman patent challenges in the first place depends in significant measure upon having the flexibility to decide when, and on what terms, to resolve the litigation rather than fight "to the death" in every case. *See, e.g.*, *Valley Drug*, 344 F.3d at 1299, 1308; *Asahi Glass*, 289 F. Supp. 2d at 994.

The reason is simple. When deciding whether to file an ANDA challenging a patent, a generic company must weigh the cost of the litigation that will inevitably result from that ANDA filing. *See, e.g.*, Bret M. Dickey & Daniel L. Rubinfeld, *Would the* Per Se *Illegal Treatment of Reverse Payment Settlements Inhibit Generic Drug Investment?*, 8 J. Comp. L. & Econ. 615, 622 (2012). And, as noted

above, patent litigation is expensive and time-consuming.

Generic companies have finite resources—and these resources are stretched by the multiple patent challenges that such companies typically have ongoing at any given time. *See Cipro I*, 261 F. Supp. 2d at 256. If the expected cost of a patent challenge is increased, a generic company will necessarily be able to bring fewer challenges, meaning that the company will develop fewer low-cost generic drugs—all to the clear detriment of competition. As one recent report explains:

> [I]f antitrust policy towards patent settlements reduces the ability of generic manufacturers to settle litigation and therefore increases the cost and risk associated with bringing a generic version to market, generic manufacturers' investments in these challenges are likely to be diminished. That would reduce the number of generic drugs in the future "pipeline." In the long run, a reduction in the number of generic entrants would likely lead to higher average pharmaceutical prices.

Dickey & Rubinfeld, *supra*, at 619-20.

FTC's proposed rule would have precisely this detrimental, competition-reducing effect. By reducing generic companies' ability to settle litigation, FTC's proposed rule would present generic companies with a Hobson's choice. On the one hand, the company must be prepared to litigate its patent case to the bitter end—an expensive proposition for any generic company, especially when facing a branded company who has incentive to "go to the

mat" and to spare no expense in litigating against it. Or, on the other hand, it must trade that patent litigation for antitrust litigation (and the specter of treble damages). The result would necessarily be fewer patent challenges and the development of fewer generic drugs. *See, e.g.*, *Cipro I*, 261 F. Supp. 2d at 256 ("To maximize [the] incentives [for generic investment in product development and patent challenges], a generic company should be permitted to choose not only when to commence patent litigation, but also when to terminate it. Otherwise, the incentives to mount an ANDA IV challenge could be reduced."); Dickey & Rubinfeld, *supra*, at 624 ("Without the ability to settle, such substantial [litigation] uncertainties can dramatically chill the incentives of a generic manufacturer to develop generic drugs."). And, of course, fewer patent challenges and reduced generic drug development mean fewer generic drugs on the market, which will directly impact consumers.

That is why, as Judge Posner has recognized, "[a] ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive." *Asahi Glass*, 289 F. Supp. 2d at 994. By contrast, "[e]nsuring that generic manufacturers have a viable option to settle patent litigation"—which the scope of the patent test does—"reduces the uncertainty associated with investing in a new generic drug and, all else equal, increases generic manufacturers' incentives to invest in new drugs." Dickey & Rubinfeld, *supra*, at 624. And this "[i]ncreased competition from generic manufacturers leads to lower drug prices." *Id.*

Experience bears this out. When courts began to apply the scope of the patent test, the number of patent challenges increased dramatically: "a record 65 new first-to-file lawsuits [were filed] in 2009, up from 51 in the prior year and more than double the number just three years ago." RBC Capital Markets, *Pharmaceuticals: Analyzing Litigation Success Rates* 1 (Jan. 15, 2010). By contrast, in prior years, when settlements with monetary consideration were considered anticompetitive by certain courts, there were far fewer patent challenges. *See id.* In short, while the scope of the patent test promotes certainty and, with it, competition, FTC's proposed rule would reduce patent challenges and significantly harm consumers.

Apotex, an *amicus* supporting FTC, takes issue with the scope of the patent test and argues that FTC's proposed rule severely restricting settlements is justified because only one generic manufacturer has incentive to challenge a patent—the one that files the first ANDA with a Paragraph IV certification and is thereby eligible for a 180-day period of marketing exclusivity. Apotex also argues that provisions included in certain Hatch-Waxman settlements (referred to by Apotex by the misnomer "poison pill"), which permit a settling party to enter the market if any other party successfully challenges the patent, further disincentivize subsequent challengers. *See* Br. of Apotex, Inc. as *Amicus Curiae* Supporting Petitioner ("Apotex Br.") 7-21. But Apotex's arguments ignore the reality of Hatch-Waxman challenges and Apotex's own conduct.

As an initial matter, when a generic manufacturer makes the decision to devote resources

to develop a generic version of a branded drug, that manufacturer does not know which company will be the first to succeed and file an ANDA with a Paragraph IV certification—indeed, that is often discovered well *after* a Paragraph IV patent challenge is filed. But the generic manufacturer does understand, and takes into account, the probable costs of that challenge, including litigation. And, as explained above, if litigation costs increase (because settlement options are restricted), generic manufacturers will choose in some cases not to even attempt to develop a generic drug.[7]

But even if a generic manufacturer knew that it would not be the first Paragraph IV ANDA filer, that company would still be incentivized to challenge the branded company's patent. A subsequent filer, like a first-filer that is not sued by a branded company, can file a declaratory judgment action and trigger the first-filer's 180-day exclusivity period via the Hatch-Waxman Act's court-decision trigger, and thereafter launch its own generic product. Indeed, this is exactly what the Hatch-Waxman Act contemplates. *See, e.g.*, *Teva Pharm., USA, Inc. v. FDA*, 182 F.3d 1003, 1007-08 (D.C. Cir. 1999); *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1073-74 (D.C. Cir. 1998); *see also Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1294-96 (Fed. Cir. 2008). Numerous

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[7] Tellingly, Apotex has itself previously opined that "*[r]everse payments are not the cause of the settlement problem.*" Apotex Inc., *Patent Settlements Between Brand and Generic Pharmaceutical Companies* 1 (2009) (emphasis in original), *available at* http://www.fdalawblog.net/files/apotex---parked-excl.pdf.

Hatch-Waxman cases are litigated between branded companies and generic companies that are not entitled to exclusivity.[8]

Moreover, Apotex's argument that such incentives are ineffective is belied by its own conduct. In the very case it references—*In re Modafinil*—Apotex was not one of the four first-filer generic manufacturers and the agreement contained a so-called "poison pill" provision; nevertheless, Apotex not only filed an ANDA, it later made a Paragraph IV patent challenge and filed a declaratory judgment action. *See* Apotex Br. 20. Likewise, as noted above, in the *Tamoxifen* and *Cipro* litigation, despite the fact that the first-filer entered into a settlement agreement, multiple other companies challenged the patents in court (and all subsequent challengers lost). *Tamoxifen*, 466 F.3d at 194-95; *Cipro Fed. Cir.*, 544 F.3d at 1328-29. In short, Apotex's arguments about incentives have no merit. Indeed, its real complaint is not with the settlement of litigation at all, but rather, with the operation of the Hatch-Waxman Act itself. But such allegations are not cognizable and are directed to the wrong forum. If Apotex dislikes the operation of the Hatch-Waxman regulatory regime, it must petition Congress, not the courts, to change it.

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[8] Furthermore, the term "poison-pill clause" is simply wrong. *See* Apotex Br. 17-18. The clause to which Apotex refers does no more than allow a settling generic company to enter the market *even earlier* than it otherwise could, thereby *increasing* the total number of competitors in the market if a patent is invalidated. Such clauses are the very definition of pro-competitive.

Ultimately, experience proves that the Hatch-Waxman regime is not broken, and the Court should reject FTC's flawed approach, which would reduce the incentives for generic manufacturers to bring patent challenges, reduce overall competition, and harm consumers.

CONCLUSION

For the foregoing reasons, the Court should affirm the decision below.

Respectfully submitted,

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AMICUS CURIAE BRIEF

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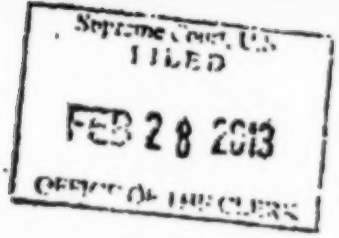

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IN THE

Supreme Court of the United States

FEDERAL TRADE COMMISSION,

Petitioner,

v.

ACTAVIS, INC., ET AL.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF FOR THE GENERIC PHARMACEUTICAL ASSOCIATION AS AMICUS CURIAE SUPPORTING RESPONDENTS

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INTEREST OF THE AMICUS CURIAE

The Generic Pharmaceutical Association (GPhA) is a nonprofit, voluntary association representing nearly 100 manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. GPhA's members provide American consumers with generic drugs that are just as safe and effective as their brand-name counterparts, but substantially less expensive. GPhA members' products account for roughly 80% of all prescriptions dispensed in the United States but only 27% of the money spent on prescriptions. In this way, the products sold by GPhA members save consumers nearly $200 billion each year. GPhA's core mission is to improve the lives of consumers by providing timely access to affordable pharmaceuticals. GPhA regularly participates in litigation as *amicus curiae*, taking legal positions that are adopted by GPhA's Board of Directors and reflect the position of GPhA as an organization. *See, e.g.*, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, No. 10-844; *PLIVA, Inc. v. Mensing*, No. 09-993.[1]

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[1] All parties have consented to the filing of this brief. A letter reflecting petitioner's consent is on file with the Clerk, and letters reflecting respondents' consent are being lodged with this brief. No counsel for a party authored this brief in whole or in part. No party, no counsel for a party, and no person other than *amicus*, its members, and its counsel made a monetary contribution intended to fund the preparation or submission of this brief.

SUMMARY OF ARGUMENT

Consumers benefit when a brand-name drug company that is seeking to exclude a generic competitor for the full term of a patent agrees to halt its litigation and allow early entry of a generic drug. This Court should reject the FTC's argument that whenever such settlements should be declared presumptively unlawful under the "quick look" doctrine whenever they include a so-called "reverse payment." As the court below properly recognized, the inclusion of some form of payment does not change the fact that the settlements did not restrain any trade beyond the scope of the patent, and therefore was permissible under both the patent laws and the antitrust laws.

The FTC's arguments for reversal fail for both legal and factual reasons. "[A]ntitrust analysis must sensitively recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies." *Verizon Commc'ns v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411-12 (2004) (quoting *Concord v. Boston Edison Co.*, 915 F.2d 17, 22 (1st Cir. 1990) (Breyer, C.J.)). The FTC acknowledges that principle (Br. 30), but the FTC's effort to apply it here is fundamentally flawed. Indeed, the linchpin of its entire argument—the assertion that these settlements are analogous to naked price-fixing agreements (Br. 20, 34)—is a staggering oversimplification that ignores the economic, legal, and regulatory context in which these settlements occur.

The issues presented in this case involve the complex interplay of numerous factors, including: (1) a patent-holder's exclusionary rights, which threaten to delay generic entry to a date far later than the

early entry afforded by the settlement being challenged; (2) the intricate regulatory structure of the Hatch-Waxman Act (formally, the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585), which influences almost every aspect of competition in the pharmaceutical industry; and (3) the economics of the generic drug industry, including the need to preserve adequate incentives for generic companies to invest in future patent challenges to continue their work in speeding the entry of generic drugs to market. Given the complexities involved, it is hard to imagine a situation *less* suited to presumptive condemnation under the "quick look" doctrine.

Hatch-Waxman is designed not to foment litigation for its own sake, but "to speed the introduction of low-cost generic drugs to market." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012). Under Hatch-Waxman, a patent claim generally blocks FDA from approving a generic drug. When a generic challenges such a patent claim, what matters is that the challenge succeeds in facilitating early entry, not whether that result was achieved by litigation to judgment or by settlement. Hatch-Waxman explicitly recognizes settlement as a valid basis for a court to lift the patent-based restrictions that bar FDA from approving a generic drug application. Allowing the generic product to come to market before the patent expires is a pro-competitive result, even if the settlement includes some form of compensation to the generic company in addition to a compromise entry date.

In this brief, GPhA addresses several key aspects of the industry—and the economic and legal consid-

erations unique to it—that are overlooked or mischaracterized by the FTC and its *amici*. A correct understanding of these industry factors makes it even more clear that the FTC's reliance on the "quick look" doctrine is entirely unfounded and should be rejected.

A. Settlement agreements promote competition by allowing a generic product to come to market before the end of the patent term. Generic competition reduces drug prices dramatically: on average, a generic drug costs about one-third as much as its brand-name equivalent. But a brand-name company that prevails in patent litigation can exclude generic competition and continue to charge higher prices for the term of the patent. A settlement brings about generic entry during the patent term—providing dramatic savings to consumers. Settlements also ensure that generic drug manufacturers earn a return on their investment in challenging a brand's patent in the first place. That return on investment, in turn, enables generic manufacturers to continue bringing new generic drugs to market, including by challenging new brand-name drug patents.

B. The FTC dismisses these pro-competitive benefits based on a flawed assessment of the risks that patent litigation entails. The FTC's basic point is that, although a settlement may allow the generic defendant to enter the market before the end of the patent term, the generic might have been able to enter the market even sooner, *if* it had won the litigation. But under real-world conditions, generic defendants cannot count on the lopsided chance of winning that the FTC portrays. While generic drug companies have won many important victories,

speeding up the entry of lower-cost generic medicines, brand-name companies also have won a significant number of cases, successfully asserting their patents to block generic entry until the patents expire. The FTC's assertion that generics win three-quarters of the cases litigated to conclusion (Br. 6-7) is based on outdated information; current data show that the generic "win" rate is slightly less than 50%.

Settlements replace substantial litigation risk with certainty: the generic manufacturer can obtain guaranteed entry before the patents expire. And that certainty confers a concrete, pro-competitive benefit. The FTC acknowledges (Br. 40) that under its proposed treatment of "reverse payment" settlements, some cases that would otherwise have settled will instead be litigated to judgment. And as the statistics suggest, in a significant number of those cases the generic challenger would lose and, as a result, would be barred from entering the market until the relevant patents had expired. *See* 35 U.S.C. § 271(e)(4)(A). In other words, in those cases, the FTC's rule will cause generic entry—competition—to occur *later* than a settlement entry date, not sooner. No principle of antitrust law supports that result.

C. Nor does a single settlement protect a patent from additional challenges. The generic market is competitive, and other generics are free to file their own ANDAs challenging the patent. Even when one company settles, other generic companies have significant incentives to challenge the same patent so that they can bring their own products to market. And the incentives work: experience shows that generic companies, including those who do not qualify for the special incentive that Hatch-Waxman be-

stows on "first filers," continue to litigate patent challenges even after the brand-name company has settled with a first filer. If those challenges succeed, the regulatory structure ensures that generic entry can occur within days and will not be blocked by a prior settlement agreement, accelerating entry for everyone. The court below properly recognized this dynamic and correctly understood that it mitigates any competitive concerns about "reverse payment" settlement agreements. Pet. App. 35a-36a.

D. A proper understanding of the risks involved in the patent litigations being settled, of the operation of the relevant FDA laws, and of the actual experience of the industry thoroughly dispels any suggestion that "reverse payment" settlements can properly be branded as presumptively anticompetitive under a "quick look" analysis. *See Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 771 (1999) ("quick look" review is reserved for cases where anticompetitive effect is "obvious"). To the contrary, all the relevant regulatory, legal, and economic evidence demonstrates that these agreements are *procompetitive* and should be sustained. Adopting the FTC's rule will delay generic entry and deter future patent challenges by generic companies who have fewer options to settle costly patent litigation on terms that will justify investing in the patent challenge to begin with. That result hurts both competition and consumers.

ARGUMENT

A full understanding of the generic drug industry, and the legal and economic incentives that govern it, dispels the FTC's arguments. The FTC asserts that settlements of patent litigation containing a "reverse payment" are so obviously analogous to naked re-

straints of trade that they deserve no more than a "quick look" before condemnation. As we explain below, in the context of settlements of Hatch-Waxman litigation, the FTC's analogy does not hold true at all (much less obviously so). Patent claims are an obstacle to competition that is inherent in every Paragraph IV case. Settlements remove that obstacle and bring competition to the market even while patents are still in force. Eliminating reverse payments means precluding some cases from settling—resulting in needless litigation, delayed competition, and higher prices.

I. Generic Drugs Create Competition And Benefit Consumer Welfare Every Time They Enter The Pharmaceutical Market

The nearly 30 years of experience with Hatch-Waxman can only be called a success. A vibrant generic drug industry makes available high quality, safe, and less expensive medicines to patients and providers in the United States. As the FTC acknowledges (Br. 45), the generic drug industry also is fulfilling the intent of Hatch-Waxman in challenging patents on brand-name drug products when it is appropriate to do so. As with all types of civil litigation, many of the patent cases between brand and generic companies result in settlements, which invariably permit generic drugs to come to market sooner than they would have if the patent case had proceeded to judgment and the generic company had lost. These settlements have contributed importantly to the enormous savings generated by the availability of generic drugs.

A. The Availability Of Generic Drugs Saves Consumers Money And Increases Consumer Access To Lifesaving Therapies

Generic drugs are therapeutically equivalent to their brand-name counterparts. To be approved by FDA, a generic drug must contain the same active ingredients as a brand-name drug, in the same dosage strength and form, and the drug must be absorbed by the body in the same ways. *See* 21 U.S.C. § 355(j)(2)(A)(ii), (iv). Upon approval, FDA certifies that a generic drug is safe and effective for its intended uses, just as FDA does for brand-name drugs. Because the generic drug is therapeutically equivalent to its counterpart in every relevant sense, it does not need to undergo the same clinical testing before approval. *See, e.g.*, *Caraco*, 132 S. Ct. at 1676; FDA, *Generic Drugs: Questions and Answers*, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm (last updated Aug. 24, 2011).

A generic drug manufacturer starts the approval process for a new drug by filing an Abbreviated New Drug Application ("ANDA") with FDA. The application demonstrates that the new drug is identical in the relevant respects to a drug that FDA has already approved. 21 U.S.C. § 355(j)(2)(A). FDA may disapprove the application only on grounds specified in the statute. *Id.* § 355(j)(4).

Generic drugs are substantially less expensive than brand-name drugs, in part because of the efficiencies generated by this streamlined approval pathway. The average generic drug costs only about one-third as much as the average brand-name drug. GPhA, *Economic Analysis: Generic Pharmaceuticals*

1999-2008: $734 Billion in Health Care Savings 5 (May 2009). That cost saving was precisely why Congress, in adopting the Hatch-Waxman Act, sought to encourage generic-drug applications. *See, e.g.*, *Caraco*, 132 S. Ct. at 1676. Today, when the rising cost of health care remains one of the most pressing national issues, the ability to develop and market cost-effective generic drugs is all the more important.

Consumers have responded overwhelmingly to the ready availability of low-cost generic drugs. About 4 billion prescriptions were written in 2011; more than 3.2 billion of them—roughly 80%—were dispensed with generics. GPhA, *Generic Drug Savings in the U.S.* 2 (4th ed. 2012). Indeed, when equivalent branded and generic drugs were both available, the generic was purchased 94% of the time. *Id.* at 3. All told, the availability of generic drugs saved the U.S. health care system more than $1 trillion over the course of the last decade—nearly $200 billion in 2011 alone. *Id.* at 1; *see also, e.g.*, Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* 31 (July 1998).

B. Patents Are A Substantial Obstacle To Generic Competition

None of these benefits can be realized, however, until the brand-name manufacturer's patent claims are resolved. Under Hatch-Waxman, even if FDA is prepared to approve a generic drug as safe and effective, a brand-name manufacturer's patent claims put the approval on hold for a period of time while the brand-name and generic manufacturers litigate. *Caraco*, 132 S. Ct. at 1676. And if the generic manufacturer loses, it cannot win approval of its drug un-

til after the patent expires. Settlements provide a certain resolution to that problem: they bring the costly litigation to a close, and they guarantee that consumers will reap the benefits of generic competition as of a date certain, before the patent expires.

When a brand-name manufacturer submits a new drug application, it must include a listing of patents: every patent that claims the drug or a method of using it and that the patentee could reasonably assert would be infringed by the manufacture, offer for sale, or sale of a generic version of the drug. 21 U.S.C. § 355(b)(1). FDA maintains an electronic compilation known as the Orange Book (formally, "Approved Drug Products with Therapeutic Equivalence Evaluations"), which contains the number, expiration date, and certain other information for each listed patent. Listing patents in the Orange Book creates a substantial hurdle to generic competition on the claimed product.

When a generic drug manufacturer submits an ANDA for a generic that is bioequivalent to a drug with patents listed in the Orange Book, the manufacturer must advise FDA of how it plans to deal with the listed patents. If a patent is still in force, then the manufacturer must either agree to wait for FDA approval until the patents expire, *id.* § 355(j)(2)(A)(vii)(III), or must certify that the patent is invalid or will not be infringed by the proposed generic. *id.* § 355(j)(2)(A)(vii)(IV). The latter option is known as a "Paragraph IV certification." The patentee must be notified of any such filing, and it may—and usually does—file a patent-infringement action without further ado. *Id.* § 355(j)(2)(B); 35 U.S.C. § 271(e)(2)(A) (providing that merely filing the

ANDA constitutes patent infringement, without the need to wait until the ANDA is approved or the generic drug is made or sold). If the patentee files suit, then the ANDA may not be approved—even if FDA is ready to declare the drug safe and effective—until 30 months go by[2] or a court rejects either the patent itself or the claim of infringement. 21 U.S.C. § 355(j)(5)(B)(iii). If the patentee wins, then the generic manufacturer's ANDA cannot be approved until the patent expires. *Id.* § 355(j)(5)(B)(iii)(II)(bb); 35 U.S.C. § 271(e)(4)(A).

If the parties reach a settlement, however, the obstacle is removed and generic competition may begin. Hatch-Waxman expressly recognizes two circumstances under which FDA may approve the generic immediately: if the generic wins a court decision (a "judgment" of a district court, or a decision of a court of appeals), *or* the parties reach a settlement (a "settlement order or consent decree") that permits the generic to go forward. 21 U.S.C. § 355(j)(5)(B)(iii)(I), (II). Thus, Hatch-Waxman's explicit terms recognize settlements as a valid basis for terminating the patent challenge and authorizing FDA approval of a generic drug prior to patent expiration.

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[2] If the litigation is still pending 30 months after the Paragraph IV certification, FDA may approve the ANDA, at least pending any court decision that the patent is valid and infringed. But the generic manufacturer still faces substantial disincentives to actually begin selling the approved drug in that posture (known as "launching at risk"): if it loses the patent litigation before it begins selling its product on the market, it is subject only to injunctive relief, but if it loses *after* it begins selling, it is also subject to substantial damages liability. 35 U.S.C. § 271(e)(4)(C).

C. Settlements That Permit Early Entry Improve Consumer Welfare

When settlements lock in generic entry before a patent expires, the benefit to competition and to consumers is often quite dramatic. For example, generic equivalents of Lipitor, the best-selling prescription medicine of all time, became available in November 2011 due to patent settlements. If, instead of settling, the parties had proceeded with the patent litigation and the brand had won, generic entry would not have occurred until early 2017.[3] Introducing a lower-cost alternative, more than five years early, to the world's best-selling drug is projected to save consumers as much as $4.5 billion per year by 2014.[4]

GPhA's members have obtained similar results for a growing volume of drugs. One GPhA member estimated in 2009 that in total, its settlements had "removed 138 years of monopoly protection" and thereby provided $128 billion in savings to consumers through early generic entry. *See* Teva Pharms. USA, Press Release, *Teva Pharmaceuticals Issues Statement in Response to Federal Trade Commission Claims on Patent Settlements* (June 24, 2009), http://tinyurl.com/TevaStatement.

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[3] *See* Pfizer Inc., Press Release, *Pfizer and Ranbaxy Settle Patent Litigation Worldwide* (June 18, 2008), http://www.pfizer.com/news/press_releases/pfizer_press_release_archive.jsp?guid=20080618005386en&source=2008&page=6; FDA, *Patent and Exclusivity Search Results*, http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=020702&Product_No=001&table1=OB_Rx (last updated Feb. 26, 2013).

[4] *See* Cynthia A. Jackevicius et al., *Generic Atorvastatin and Health Care Costs*, 366 New Eng. J. Med. 201 (2012).

In fact, when one generic manufacturer settles and the others litigate, it is frequently the case that the settlement, not the litigation, will produce the better result for consumers. For example, four different generic manufacturers filed Paragraph IV certifications seeking to manufacture generic tamoxifen citrate, a breast-cancer treatment that was then the world's most widely prescribed anticancer medication. The brand-name manufacturer sued all four to enforce its patent. The first generic manufacturer to file its certification, Barr Laboratories, ultimately reached a settlement allowing it to market tamoxifen under its own label, nine years before the patent expired. The three other generic manufacturers litigated their cases to conclusion, but were unsuccessful. "In each case, the court . . . upheld the validity of [the brand-name manufacturer's] tamoxifen patent." *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 195 (2d Cir. 2006), *cert. denied*, 551 U.S. 1144 (2007); *see id.* at 190, 193-95.

The unsuccessful court challenges to the tamoxifen patent illustrate the tangible consumer benefit from Barr's settlement. Nine years before the patent expired, Barr was able to bring a cheaper version of tamoxifen to market. *See id.* at 194-95 & n.9. If Barr had instead litigated to final judgment and lost as the other companies did, the brand-name manufacturer would have faced no generic competition for nine more years.

II. Patents Pose Significant Risks That Can Delay Generic Entry, And Settlements Mitigate Those Risks To The Benefit Of Consumers

The settlements at issue in this case undeniably bring the very real benefits of generic-drug competition to consumers sooner than the pharmaceutical patent would allow. To call that pro-competitive effect anticompetitive, the FTC treats as a solid baseline what is really an uncertain bet: *if* a generic manufacturer could persuade a district court and the Federal Circuit that none of the relevant patents allows the brand-name manufacturer to exclude the generic from the marketplace, then the generic would come to market even sooner—perhaps immediately. But that *if* represents an enormous risk for generic manufacturers. It will not necessarily come to pass; it will not even presumptively come to pass. As we show in detail below, current data demonstrate that generic manufacturers lose as many challenges to drug patents as they win. And with each loss, consumers are deprived of the benefit of generic-drug competition until the full expiration of the patent's term. Settlements like those at issue here avoid that risk and bring consumers a definite benefit: the *certainty* of greater competition and lower prices before the patents expire. The antitrust laws should encourage that result, not condemn it.

A. Generic Manufacturers Face Substantial Litigation Risk, Losing As Often As They Win

The FTC dismisses the hastening of competition by five years as "irrelevant" to the question of competi-

tion law presented here. Br. 43 n.10.[5] That position is premised on the FTC's assumption that a generic applicant likely would have won in the litigation and been able to enter the market on an earlier date than the settlement permits. *See* FTC Br. 4, 6-7, 44. Any such assumption is belied by the empirical data and should be rejected.

GPhA's members have achieved important successes by challenging patents in court and bringing generic drugs to market sooner than the patents would allow. *See, e.g., Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955 (Fed. Cir. 2001) (Prozac). It is equally true, however, that brand-name drug manufacturers have prevailed in a large number of patent cases arising under Hatch-Waxman, successfully enforcing their patents to prevent generic entry until after the full term of their patents had expired.

In suggesting that generics' patent challenges are mostly successful, the FTC relies principally on data that is more than a decade old. *See* FTC Br. 4, 6-7, 44. In particular, the FTC relies on its own 2002 *Generic Drug Study*—which examined only 40 drug products—to assert that generic drug manufacturers have won "nearly three quarters of the time" in litigated patent cases. *Id.* at 6. More recent and comprehensive data paint a very different picture.

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[5] The FTC contends that because the scope-of-the-patent test might hypothetically allow a settlement to provide for generic entry only at the end of the patent term, the law instead should presumptively condemn *real* agreements, like those in this case, that provide for competition *before* the end of the patent term. As we show in this brief, agreements providing for early entry are the norm, particularly because of the incentives created by competition from multiple ANDA filers and the potential to forfeit exclusivity. *See infra* pp. 27-32.

According to a study from 2010, which analyzed cases that had been litigated over the prior decade, generics prevailed in 82 cases and lost in 89 cases, for a generic "win" rate in litigated cases of 48%. RBC Capital Mkts., *Pharmaceuticals: Analyzing Litigation Success Rates* 4 (Jan. 15, 2010), http://amlawdaily.typepad.com/pharmareport.pdf. These data do not support any presumption that continuing to litigate patent cases, rather than permitting the parties to settle with an agreement that permits generic entry prior to patent expiration, would benefit competition.

Moreover, generic challengers face substantial risks without regard to the type of patent at issue or the nature of the challenge. The FTC describes certain types of patents—such as those claiming a formulation or a method of using a drug, as opposed to those claiming the chemical compound itself—as "secondary patents" and asserts that such patents "may be particularly susceptible to being avoided, in whole or in part, by generic competitors." FTC Br. 7. Once again, the FTC's assertion is overstated. A review of Federal Circuit decisions in Hatch-Waxman cases between 2010 and 2012 shows that: (1) generics did not win any validity challenges[6] to patents covering the chemical compound of the medicine; (2) generics won 7 challenges[7] to the validity of formula-

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[6] *In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511 (Fed. Cir. 2012); *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 689 F.3d 1368 (Fed. Cir. 2012); *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280 (Fed. Cir. 2012); *Daiichi Sankyo Co. v. Matrix Labs., Ltd.*, 619 F.3d 1346 (Fed. Cir. 2010).

[7] *Tyco Healthcare Grp. LP v. Mutual Pharm. Co.*, 642 F.3d 1370 (Fed. Cir. 2011); *Duramed Pharm., Inc. v. Watson Labs., Inc.*, 413 F. App'x 289 (Fed. Cir. 2011); *AstraZeneca LP v. Apotex,*

tion or method-of-use patents but lost 5 challenges[8] to such patents; and (3) generics won 4 non-infringement defenses[9] to formulation or method-of-use patents but lost 3 non-infringement defenses[10] to such patents. These examples show that, even as to these so-called "secondary patents," generic drug manufacturers still face real and substantial litigation risk.

Experience also shows that generic drug challengers face significant risks even if they prevail in district court, which permits the FDA to approve an ANDA so the generic can commence sales. The Federal Circuit's willingness and propensity to disagree with district courts has been well documented. For example, one recent study compared the Federal Circuit (limited to patent cases) and representative re-

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Inc., 633 F.3d 1042 (Fed. Cir. 2010); *King Pharms., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267 (Fed. Cir. 2010); *Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381 (Fed. Cir. 2010); *ALZA Corp. v. Andrx Pharms., LLC*, 603 F.3d 935 (Fed. Cir. 2010); *Purdue Pharma Prods. L.P. v. Par Pharm., Inc.*, 377 F. App'x 978 (Fed. Cir. 2010).

[8] *Pozen Inc. v. Par Pharm.*, 696 F.3d 1151 (Fed. Cir. 2012); *In re Cyclobenzaprine Hydrochloride Extended Release Capsule Patent Litig.*, 676 F.3d 1063 (Fed. Cir. 2012); *Unigene Labs, Inc. v. Apotex, Inc.*, 655 F.3d 1352 (Fed. Cir. 2011); *Eli Lilly v. Actavis Elizabeth LLC*, 435 F. App'x 917 (Fed. Cir. 2011); *Mitsubishi Chem. Corp. v. Barr Labs., Inc.*, 435 F. App'x 927 (Fed. Cir. 2011).

[9] *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316 (Fed. Cir. 2012); *Duramed Pharm., Inc. v. Paddock Labs., Inc.*, 644 F.3d 1376 (Fed. Cir. 2011); *Reckitt Benckiser Inc. v. Watson Labs., Inc.*, 430 F. App'x 871 (Fed. Cir. 2011); *In re Brimonidine Patent Litig.*, 643 F.3d 1366 (Fed. Cir. 2011).

[10] *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 616 F.3d 1283 (Fed. Cir. 2010); *Eli Lilly*, 435 F. App'x at 926-27; *Pozen*, 696 F.3d at 1167-72.

gional circuits and found that the Federal Circuit was more than twice as likely to reverse a district court decision. Ted L. Field, *"Judicial Hyperactivity" in the Federal Circuit: An Empirical Study*, 46 U.S.F. L. Rev. 721, 757, 758, 760 (2012).

Even an appellate decision does not resolve the litigation risk. In 2004, for example, an ANDA applicant won a ruling in the district court that certain patents claimed to cover the blockbuster pain medication Oxycontin were unenforceable. *See Purdue Pharma L.P. v. Endo Pharms. Inc.*, 438 F.3d 1123, 1128 (Fed. Cir. 2006). Several generic manufacturers started selling their products; others followed after a panel of the Federal Circuit affirmed the judgment of unenforceability in 2005. But a year later, on the brand company's petition for rehearing, the Federal Circuit panel vacated its decision and reversed the finding of unenforceability. *See id.* at 1126. On remand, moreover, the district court held that the patents at issue were valid, enforceable, and infringed. As a result, the generic drug manufacturers suddenly faced exposure to potentially enormous damages claims.[11] Many other similar situations have occurred over the past several years.

Until a patent case is litigated through the court of appeals, therefore, a generic applicant continues to face significant litigation risks. Success in the dis-

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[11] The potential damages exposure to a generic drug company in this type of situation could exceed the company's entire profits from selling its product, even in the absence of a claim for enhanced damages. As the FTC notes (Br. 21), the profits that a brand company loses upon generic entry often exceed the profits earned by the generic company.

trict court provides little security, especially on matters reviewed *de novo* on appeal.

B. Restricting The Ability To Settle Threatens To Disrupt The Overall Generic Marketplace

Generic manufacturers enter this risky terrain only after careful analysis of the potential gains if they prevail and the potential exposure if they lose. The cost, length, and uncertainty of litigation represent the chief obstacles to entering the market with a Paragraph IV certification. Settlements are a key way of overcoming those obstacles and bringing competing pharmaceuticals to market sooner—the goal of Hatch-Waxman. In some instances, generic manufacturers can and do settle cases solely by agreeing on a compromise entry date. But even the FTC concedes (Br. 40) that sometimes no such agreement is possible—and thus no settlement is possible—without some additional consideration. By taking consideration off the table through the threat of antitrust liability for anything that even resembles a payment, the FTC's proposed rule would make settlements more difficult and, in some cases, impossible to achieve. Adopting such a rule would drive up the expected cost of Paragraph IV litigation. It would delay generic entry in every case that leads to judgment for the brand-name plaintiff instead of a settlement. And it would decrease the number of challenges generic companies will be willing to make.

When a generic manufacturer is deciding whether to file a Paragraph IV certification to seek approval for a new generic drug that is claimed by a patent, the manufacturer must consider the cost of defending the all-but-inevitable patent-infringement action.

See, e.g., *Protecting Consumer Access to Generic Drugs Act of 2007: Hearing Before the Subcomm. on Commerce, Trade, and Consumer Protection of the H. Comm. on Energy and Commerce*, 110th Cong. 136 (2007) (statement of Theodore Whitehouse). That price can be extremely high, particularly given the high stakes for the brand-name patentee seeking to protect blockbuster profits from generic competitors. One estimate puts the average cost of a single ANDA litigation at about $10 million.[12]

The availability of settlements is indispensable to managing these costs, because the possibility of settling decreases the chances that the generic will end up incurring the litigation costs but gaining nothing—which is what happens if the patentee prevails at the end of the litigation. And the ability to include valuable consideration in the negotiation increases the chances that a settlement can be worked out. That is particularly important in the context of a dispute between brand-name and generic pharmaceuticals, because their very different business models causes them to value potential entry quite differently. If, as the FTC suggests, the only permissible settlement tool is a calendar—the parties may bargain over a compromise entry date, but neither party may offer additional consideration as a way to bridge the gap between the parties' differing views of the strength of the patent—the parties in many cases simply will be too far apart to reach agreement.

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[12] Michael R. Herman, Note, *The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation*, 111 Colum. L. Rev. 1788, 1795 n.41 (2011) (citing Marc Goodman et al., Morgan Stanley Equity Research, *Quantifying the Impact from Authorized Generics* 9 (2004)).

The FTC's own statistics bear out this point. Many settlement agreements in Paragraph IV cases do not contain any term that the FTC would characterize as a reverse payment. That does not mean that reverse payments are unnecessary to secure agreement. To the contrary, it is evidence that such payments are used when they *are* necessary and the alternatives, such as simply bargaining over the entry date, have failed.

Depriving manufacturers of the ability to settle would raise the cost of Paragraph IV litigation. If each case must be litigated all the way to trial, and likely through a Federal Circuit appeal as well, the price of entry will go up substantially. That, in turn, will decrease the number of such cases generic drug companies will be willing to undertake. Pharmaceutical companies need to know *before* they file their ANDAs whether they can settle Paragraph IV cases, and if so, on what sort of terms. If the ability to bargain for settlement becomes so restricted that, in many cases, there will be no ability to settle at all, generic drug companies will bring fewer patent challenges and consumers will have to wait longer to obtain lower-cost medicines.

III. Patent Settlements Under Hatch-Waxman Do Not Impede Competition Among Generics

Hatch-Waxman's goal is promoting consumer access to affordable generic drugs—not merely promoting litigation to challenge drug patents, as the FTC believes (Br. 30-33). *Caraco*, 132 S. Ct. at 1676. Evaluating whether settlements serve the statutory purpose cannot focus narrowly on whether a single Paragraph IV case settles or proceeds to trial, be-

cause Paragraph IV litigation involves multiple players and vibrant competition on the generic side. If one company settles, consumers are guaranteed early access to a low-cost generic drug. And if that company's generic competitors continue to litigate, as they often do, consumers stand to benefit even further. Definite early entry by a settling generic, on the one hand, and the possibility of *immediate* entry by a litigating generic, on the other, are both positives.

The FTC and its *amicus* Apotex discount the effect of competition on the generic side, based on a misconception about the legal significance of filing the first Paragraph IV certification. Although Hatch-Waxman gives "first filers" a period of exclusive marketing as an incentive to file a Paragraph IV challenge, the FTC and Apotex are demonstrably incorrect in suggesting that *only* one first filer will challenge the patent in litigation—and that the brand-name company can insulate its patent simply by settling with the first generic challenger. That simplistic assumption is not consistent with either the statute or the facts. Even if one generic manufacturer reaches a settlement in order to manage the risk and uncertainty associated with Paragraph IV litigation, there are numerous reasons to expect that other generics will fight on. That single settlement does not insulate the patent from challenge; indeed, more challenges may be filed *after* the settlement.

A. Multiple Generic Companies May Claim The First-Applicant Bounty

More than one company can claim the reward of a 180-day exclusivity period and, consequently, have an incentive to litigate. Under current law, FDA

awards exclusivity based on the first day that a Paragraph IV certification is filed: all manufacturers who file ANDAs with Paragraph IV certifications on that day are "first applicants" who share the exclusivity period. 21 U.S.C. § 355(j)(5)(B)(iv); *see also* FDA, *Guidance for Industry: 180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day* (July 2003).[13] That type of simultaneous filing occurs with some frequency. It is particularly common when the brand-name drug is granted "New Chemical Entity" exclusivity, which means that FDA cannot even begin *accepting* applications for generic equivalents until a specified date. *See* 21 U.S.C. § 355(j)(5)(F)(ii); *infra* note 18. Thus, when there are multiple first filers, Hatch-Waxman gives every one of them equal incentives to pursue a patent challenge. Apotex and the FTC—relying on pre-2003 law—do not mention that broadened incentive. *See* Apotex Br. 11 (referring to exclusivity as "available only to *the* initial challenger of a drug patent") (emphasis added); *see also id.* at 4-5, 14, 16; FTC Br. 2 n.1.

The FTC suggests (Br. 52) that a brand-name company could enter into settlements with every ANDA filer. The FTC's own data show, however, that some drugs "have been subject to as many as *sixteen* first-day ANDAs with [Paragraph IV] certifications." FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* 136 (Aug. 2011), http://www.

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[13] The statute was amended to adopt this rule in 2003. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1102(a)(1), 117 Stat. 2066, 2457. The new statutory rule does not apply to any drug for which a Paragraph IV certification was made before the 2003 amendment. *See id.* § 1102(b), 117 Stat. at 2460.

ftc.gov/os/2011/08/2011genericdrugreport.pdf (emphasis added). In 2005, the average was *eleven* such ANDAs for each drug, and between 2002 and 2008, the yearly average never dropped below three such ANDAs per drug. *Id.* at 136 tbl.7-5.

As the number of first filers sharing the 180-day exclusivity grows, the idea that the brand-name manufacturer could simply settle with all of them becomes increasingly unlikely. As the court below recognized, even "monopoly profits . . . will be eaten away as more and more generic companies enter the waters by filing their own paragraph IV certifications attacking the patent," Pet. App. 36a, and allowing multiple first filers broadens the incentive to enter.

B. Subsequent Filers Continue To Press Patent Challenges

Even if a brand-name company were to settle with all first filers, those settlements would not make a vulnerable patent safe from challenge. The structure of Hatch-Waxman creates many reasons why generic drug companies who are not first filers for a particular product will nonetheless pursue Paragraph IV challenges to the brand's patents, and actual experience shows that these challenges do occur—exactly as the court below posited they would. Therefore, while the FTC tries to discount the possibility that challenges by subsequent filers will continue after a settlement (Br. 52), and Apotex baldly asserts that when a generic manufacturer does not achieve first-filer status, it "lack[s] sufficient incentives to challenge a drug patent covered by a settlement between a brand-name manufacturer and the initial generic challenger" (Br. 11), the facts are otherwise.

Apotex's own experience refutes its argument. Apotex acknowledges that it is currently litigating its ability to bring generic modafinil to market, despite not being first to file. It seeks to explain away its own conduct by claiming that it was motivated by the "unique enticement" of antitrust damages. Apotex Br. 20-21. "But for" these antitrust theories, Apotex contends, it "would have stood to gain little to nothing for its efforts in challenging the patent covering modafinil." *Id.* But modafinil is hardly the only example.

Apotex itself is currently litigating at least two other cases challenging patents for which it did not file the first Paragraph IV certification. In both cases, the first filer reached a settlement with the brand-name manufacturer. One of the settling defendants has used its period of exclusivity;[14] the other has not yet brought the drug to market.[15] But

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[14] IVAX Pharmaceuticals filed the first ANDA and Paragraph IV certification challenging the two key patents listed for budesonide inhalation suspension, an asthma treatment. *See* Am. Compl. ¶¶ 9, 12, *AstraZeneca LP v. IVAX Pharms., Inc.*, No. 1:05-cv-5142 (D.N.J. Jan. 19, 2006) (Dkt. No. 7). Apotex later filed its own ANDA, although not a Paragraph IV certification; its co-defendant has filed an ANDA as well. *See AstraZeneca*, 633 F.3d at 1046, 1047. IVAX reached a settlement with the brand-name manufacturer more than four years ago and brought the generic product to market more than three years ago. *See* Consent Judgment, *IVAX*, *supra* (D.N.J. Nov. 25, 2008) (Dkt. No. 171). All exclusivity has long since expired. Apotex has been preliminarily enjoined from marketing its product, 633 F.3d at 1042, but continues to challenge the validity of the two patents. The case is currently in trial. *See AstraZeneca LP v. Breath Ltd.*, No. 1:08-cv-1512 (D.N.J.).

[15] Mylan Pharmaceuticals filed the first ANDA and Paragraph IV certification challenging the key patent for armodafinil, a wakefulness drug. Mylan reached a settlement with the brand-

Apotex continues to litigate for the right to launch its generics. So do several other companies; Apotex has three co-defendants in one case, one in the other. It is hard to imagine clearer evidence refuting the proposition that subsequent filers will not continue to challenge patents after the first filers have settled.

Apotex's behavior is hardly unique. In fact, it is common for generic manufacturers to pursue a challenge despite the possibility of having to wait out the first filer's 180-day period of exclusivity. In the tamoxifen cases discussed above, for example, three manufacturers filed ANDAs and Paragraph IV certifications not only after Barr had become the first filer, but also *after Barr had settled* the resulting litigation and begun selling an authorized generic version of tamoxifen. *See In re Tamoxifen*, 466 F.3d at 193-95.[16] Similarly, in the litigation over ciproflaxin, four generic manufacturers filed ANDAs after Barr, the first filer, settled its Paragraph IV litigation. In both cases, the later companies lost their cases—highlighting again that settlement often will lead to earlier entry than litigating a case to the bitter end—

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name manufacturer in April 2012. *See* Mylan Inc., Press Release, *Mylan Announces Settlement Agreement for its First-to-File Generic Version of Nuvigil®* (Apr. 30, 2012), http://investor.mylan.com/releasedetail.cfm?releaseid=668495. Apotex has filed its own Paragraph IV certification, as have three other generic manufacturers. *E.g.*, Compl. ¶ 27, *Cephalon, Inc. v. Apotex Corp.*, No. 1:10-cv-695 (D. Del. Aug. 18, 2010) (Dkt. No. 1). Apotex and the three companies have continued to press their claims of patent invalidity. The trial on the parties' consolidated litigation concluded in July 2012, and the District Court's decision is pending. *In re Armodafinil Patent Litig.*, No. 10-md-2200 (D. Del.).

[16] Under the law at the time, Barr retained its 180-day exclusivity. That is no longer the case. *See infra* pp. 30-31.

but the key point here is that those companies filed their ANDAs and continued to litigate their patent challenges even though the first filer retained its 180-day exclusivity and could have invoked it if the patents had been invalidated. *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 102 & n.9 (2d Cir. 2010).

Many more examples exist.[17] The foregoing few, however, suffice to demonstrate that the FTC and Apotex are simply incorrect in asserting that settlements with first filers will effectively end any challenge to a brand company's patents by other generic companies.

The fact that these challenges actually do continue—despite Apotex's talk about subsequent filers' supposed lack of incentives—should come as no surprise. There are several reasons why generic companies continue to litigate even when they are not first filers, and that this Court can be confident they will continue to do so.

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[17] To offer just one more: Barr Labs filed the first ANDA and Paragraph IV certification challenging the key patent for budesonide capsules, a treatment for irritable bowel syndrome. *See* Compl. ¶ 18, *AstraZeneca LP v. Barr Laboratories, Inc.*, No. 1:08-cv-00305 (D. Del. May 22, 2008) (Dkt. No. 1). Barr reached a settlement with AstraZeneca in May 2010. *See* Consent Order & Judgment, *AstraZeneca v. Barr*, *supra* (D. Del. May 20, 2010) (Dkt. No. 168). Mylan filed its own ANDA and Paragraph IV certification. See Compl. ¶ 15, *AstraZeneca LP v. Mylan Pharms., Inc.*, No. 08-cv-453 (D. Del. July 22, 2008) (Dkt. No. 1). Mylan continued to litigate infringement issues and ultimately won a decision of non-infringement. *AstraZeneca LP v. Mylan Pharms. Inc.*, No. 08-cv-453, 2011 WL 2516381 (D. Del. June 23, 2011), *aff'd*, 467 F. App'x 885 (Fed. Cir. 2012).

First, at the time the generic manufacturer decides to file an ANDA, it often will not know with any certainty whether it will be first to file. Yet much of the expense of developing a new generic drug—both the formulation work to develop the product, and the legal work to develop defenses to the brand's patents—occurs *before* the ANDA is filed.

Most ANDAs can be submitted at any time, even during a period of exclusivity when they can only be tentatively approved; only certain types of ANDAs have a designated first day for submissions.[18] And FDA generally does not disclose the existence or status of an ANDA that has not yet been approved, much less confirm whether a rival ANDA was filed on the same date or earlier. *See* 21 C.F.R. § 314.430(b).

Therefore, generic manufacturers frequently make the business decision to pursue an ANDA, and make substantial investments in developing that ANDA, without knowing whether the ANDA will qualify for first-filer status. Those investments are sunk costs, and there are substantial reasons for the generic company to continue pursuing the ANDA to recoup those investments, even if it learns that it will not be the first filer.

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[18] If none of a drug's active ingredients has ever been approved before, then the manufacturer reaps a five-year period of exclusivity after the drug is approved. During that time, "no [ANDA] may be submitted," except during the last year an ANDA with a Paragraph IV certification may be filed. 21 U.S.C. § 355(j)(5)(F)(ii). In most other cases, an ANDA may be submitted at any time, even if FDA is temporarily precluded from approving it. *See* 21 U.S.C. § 355(j)(5)(F)(iii)-(v) (exclusivity precludes FDA from "mak[ing] the approval of an [ANDA] . . . effective").

The manufacturer often will learn that it is a first filer only once litigation is triggered. A generic drug manufacturer that files a Paragraph IV certification can expect to be sued within 45 days. *See* 21 U.S.C. § 355(j)(5)(B)(iii) (providing that the brand-name manufacturer may stay the approval of an ANDA by filing suit within 45 days after receiving a Paragraph IV certification). Accordingly, a decision to file is a decision to litigate, and that decision—assessing the validity and scope of the brand-name drug's patents, the potential profit from launching a new generic product, and the probability of success in patent litigation—must be made without counting on first-filer status.

Second, in 2003 Congress prescribed a number of ways in which a company that files the first ANDA may nonetheless lose its exclusivity. Thus, any subsequent filer has reason to carry on with its Paragraph IV challenge even if it does not receive the bounty of 180-day exclusivity, because the first filer ultimately may not receive it either. *See id.* § 355(j)(5)(D)(iii); *see also supra* note 13 (effective date).

For example, if the company that submits the first ANDA makes sufficient changes to its application, FDA may decline to treat the amended application as relating back to the original filing date, causing that company to lose any first-filer exclusivity. Similarly, Congress has carefully written into the statute several conditions that can be grounds for revoking (or denying) a first filer's period of exclusivity. *See* 21 U.S.C. § 355(j)(5)(D). For instance, if the first filer does not obtain approval of its ANDA during the first 30 months after applying (subject to an exception

that applies when the rules are changed during the 30 months), its exclusivity is forfeited. *See id.* § 355(j)(5)(D)(i)(IV). Rival generics can sue to enforce these "forfeiture events." *See, e.g., Mylan Labs. Ltd. v. FDA*, No. 12-cv-1637, 2012 WL 6705957 (D.D.C. Dec. 27, 2012).

Third, a subsequent filer's victory in patent litigation might accelerate the entry date of a first filer who has settled, and thus the subsequent filer's entry as well. What Apotex colorfully calls a "poison-pill clause" (Br. 5, 17, 18) is in fact just an agreement that a settling party does not give up the right to enter earlier *if* the patent is actually invalidated. The result is more competition, sooner: if the settling first filer launches earlier because of the patent ruling, then the subsequent filer can do so as well, because the 180-day exclusivity will lapse sooner.[19] That hardly qualifies as an anticompetitive result, nor does it discourage subsequent filers from litigating.

Following the 2003 amendments to the statute, if the first filer does not start selling its product within 75 days after a final court decision finding the patent(s) at issue invalid or not infringed, the first filer forfeits its exclusivity. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA). Therefore, a win by a

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[19] If Apotex's real complaint is that the subsequent filer does not itself earn the 180-day exclusivity, then Apotex's quarrel is with Congress's decision to award incentives to first filers, not with reverse payments at all. Indeed, a subsequent filer that prevails in patent litigation must wait out the first filer's 180-day exclusivity whether or not the first filer has entered into a settlement agreement containing a so-called "reverse payment." As discussed below, that brief 180-day period does not discourage subsequent filers from entering the market.

subsequent filer can lead a settling first filer to launch sooner than its settlement agreement otherwise might provide, triggering the 180-day exclusivity and removing it as a regulatory barrier to approval of the subsequent filer's ANDA. Alternatively, if the first filer does not launch its product in time, the forfeiture provisions will allow the subsequent filer's ANDA to be approved immediately. Either way, the subsequent filer's win in the patent litigation can speed up its own entry, notwithstanding a settlement by the first filer.

Fourth, and finally, focusing narrowly on the six-month exclusivity period is incorrect in any event. A patent is issued for 20 years, and because some patents are actually issued *after* the brand-name drug is approved,[20] successfully invalidating a patent could result in well over a decade of profitable participation in the generic market. The FTC argues that the majority of a first filer's profits will come from sales of a product made during the 180-day exclusivity (Br. 6), but this observation obviously has no bearing for all of the *other* generic companies that sell a product without sharing in the first filer's exclusivity. For everyone but the first filer, the profit opportunity comes from getting to market and staying in for an extended period. One of the first generic drugs approved in the wake of Hatch-Waxman was diazepam, the generic equivalent of Valium®. Barr Laboratories' ANDA was approved November 1,

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[20] *See, e.g.*, 21 C.F.R. § 314.50(i)(1)(i)(A), (4) (providing that after a new drug is approved, the brand-name manufacturer must submit any new patents within 30 days, or they will not be taken into account in considering ANDAs with respect to that drug).

1985, and several diazepam ANDAs are still active today, more than 27 years later. *See, e.g.*, FDA, *Drugs@FDA*, http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm (last updated Feb. 27, 2013) (search for diazepam). A generic manufacturer that is in it for the long haul is unlikely to be dissuaded from mounting a Paragraph IV challenge purely because another company might get a six-month "head start."

IV. Settlements' Pro-Competitive Effects Preclude Any Presumption Of Illegality

The FTC asks this Court to declare that the Sherman Act presumptively forbids *any* settlement agreement containing a "reverse payment" (whatever that may include). But as this Court has repeatedly said, the sort of "quick-look review" the FTC seeks is reserved for cases in which "the likelihood of anticompetitive effects is . . . obvious." *Cal. Dental*, 526 U.S. at 771. Quick-look review is not appropriate for cases in which the challenge conduct "might plausibly be thought to have a net procompetitive effect, or possibly no effect at all." *Id.* That is the case here.

This case arises in a highly complex and specialized regulatory context, in which a patent claim keeps the generic equivalent drug off the market while the case is litigated. The patent claim alone makes the FTC's blanket claim of anticompetitive effect dubious. But even more significantly, there is a strong—indeed, undeniable—countervailing boost to competition every time a settlement shaves years off of a patent term. In at least some cases, the FTC's rule would forestall a settlement and leave the Paragraph IV case to be litigated to judgment—potentially a judgment that blocks competition from

lower-priced generic products for the patent's full term.

This Court need not calculate for itself the net positives and net negatives of settlements like those at issue here in order to reject the FTC's position. Once it concludes that both competing claims meet the standard of "plausibility," *Cal. Dental*, 526 U.S. at 778, then under this Court's cases, that is enough to reject "quick look" review.

As the parties have explained in detail in their briefs, settlements that restrain no trade beyond the scope of the patent are not presumptively unlawful; they are not unlawful at all. GPhA agrees that the scope of the patent sets the appropriate bounds for assessing the competitive effects of the settlements at issue here: taking proper account of the role patent rights play in the competitive dynamic of Hatch-Waxman litigation, while also properly ensuring that settlements do not restrain trade outside the scope of the patent. As the court below correctly recognized, under that standard the FTC's claim in this case cannot proceed.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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FEDERAL TRADE COMMISSION,

Petitioner,

v.

ACTAVIS, INC., ET AL.,

Respondents.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

BRIEF FOR HEALTH ECONOMICS AND LAW PROFESSORS AS AMICI CURIAE IN SUPPORT OF RESPONDENTS

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INTEREST OF AMICI CURIAE

Amici curiae are professors of health economics and law.[1] A list of signatories may be found in Appendix A. The interest of amici in this case is to encourage the development of patent and antitrust law in a direction that protects the health and welfare of current and future consumers of health care.

Amici have filed this brief because Petitioner takes a strong position against reverse payment settlements of Paragraph IV challenges without adequate appreciation of the economics of the pharmaceutical industry or of drug patents. Recent health economics literature suggests that the assumptions underlying Petitioner's arguments are incorrect. If this Court accepts Petitioner's position and holds reverse payment settlements presumptively illegal, we fear that consumers may, on balance, be harmed.

Amici ask that the Court decline to hold reverse payment settlements presumptively illegal at least until courts have adequate experience with the economic impact of these settlements to expedite their treatment in antitrust cases. Amici do not object to the Eleventh Circuit's scope-of-the-patent rule.

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[1] The parties have consented to the filing of this brief. Written evidence of Respondents' consents accompanies this filing. Petitioner lodged a blanket consent with the Clerk of the Court. No counsel for a party authored this brief in whole or in part, and no person (other than amici curiae or their counsel) made a monetary contribution intended to fund the preparation or submission of this brief.

SUMMARY OF ARGUMENT

Petitioner urges the Court to hold reverse payment settlements of Paragraph IV patent challenges presumptively illegal. Petitioner requests a rule that is stronger than the usual "quick look" rule of reason. It asks the Court to permit a pioneer drug company that is party to a reverse payment settlement—the "antitrust defendant"—a limited number of defenses, *i.e.*, only two possible defenses: that the antitrust defendant's reverse payment covers only its avoided litigation costs or that the payment is consideration for unrelated property or services. FTC Br. at 17.

Amici agree with Respondent Solvay Pharmaceuticals that, because these defenses are largely impracticable, Resp. Solvay Pharm. Br. at 22, Petitioner is actually requesting that the Court hold *per se* illegal reverse payment settlements that cannot make either of these narrow defenses. To succeed, Petitioner must demonstrate that reverse payment settlements that cannot make those two narrow defenses are so likely to harm consumers that it is not worth a court's time to inquire into the value of those settlements to consumers. Petitioner is not able to make such a demonstration.

Petitioner does not explicitly offer an economic theory explaining how extending the antitrust defendant's patent harms consumers. Implicitly, however, it relies on two factual claims: (1) that the patent, by keeping drug prices high, harms consumers, and (2) that patents associated with reverse payment settlements do not encourage socially valuable innovations. Petitioner does not provide any evidence to demonstrate either claim.

Taking heed of this Court's warning that the appropriate antitrust rule for an industry must "recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies," *Verizon Commc'ns v. Law Offices of Curtis V. Trinko*, 540 U.S. 398, 411 (2004), amici provide evidence from the health economics literature that drug patents, even those associated with reverse payment settlements, both (1) do not harm consumers and (2) generate socially valuable research.

First, amici highlight a series of studies that show that drug patents do not appear to reduce consumers' access to drugs, the primary economic harm from higher drug prices. An important reason is that the vast majority of consumers have health insurance and many of those who do not currently have insurance will under the Patient Protection and Affordable Care Act. Health insurance charges consumers a copay to purchase drugs. These copays lower the price of drugs faced by patients to roughly the same level generics would charge. As a result, drugs sales are not affected by patent expiration. This is true whether the defendant's patent is associated with a reverse payment settlement or not.

Second, the high prices that a patent enables a pioneer drug company to charge do not have anticompetitive effects. Any profits that the antitrust defendant appears to make by sustaining a drug patent through a reverse payment settlement overstates the actual profits it makes because the settlement amount largely neglects expenditures incurred during the race to invent the drug. That race for research and development (R&D) is the

appropriate market for this Court to consider when assessing the antitrust defendant's market power. The R&D market, however, is competitive and dissipates patent holders' expected profits. The available evidence suggests that antitrust defendants' revenues barely cover their actual cost of capital, *i.e.*, these defendants do not make the supra-competitive profits indicative of market power. This is true even if one includes any profits defendants make through reverse payment settlements.

Third, patents in the pharmaceutical industry do not involve a tradeoff between consumers and producers. Instead, drug patents involve a tradeoff between present consumers and future consumers. The reason lies in how pharmaceutical R&D is financed. Drug companies rely on retained earnings to finance R&D because the high risk associated with drug development limits access to external financing. Thus, an existing patented drug generates revenue from current consumers that funds R&D for future drugs that benefit future consumers. Indeed, the health economics literature has found a remarkable correspondence between current revenues and current R&D expenditures, consistent with this present versus future consumer tradeoff. While antitrust law may have a preference for consumer welfare over producer welfare, careful thought is required before committing it to prefer one set of consumers over another set.

Fourth, Petitioner ignores certain benefits that patents generate in the pharmaceutical industry but not in other industries. Unlike patents in other industries, patents in the pharmaceutical industry are essential for the conduct of certain research *after*

the grant of a patent—clinical trials—that provides valuable information to consumers. Drugs are typically patented before they are tested in clinical trials. Yet without a patent no pioneer drug company would conduct a clinical trial on a drug: generic drug companies could use the results of the trial to enter the market for that drug and the pioneer drug company would not recoup the costs of the trial. Moreover, clinical trials on a drug—even if that drug is covered by a reverse payment settlement—are socially valuable because they inform patients how safe and effective that drug is. This research is post-patent, and it is valuable whether the patents are associated with reverse payment settlements or not.

Moreover, profits from a commercially successful drug—even if the patent is associated with a reverse payment settlement—offset the costs of research on commercially less successful drugs, including drugs with uncontested patents. Because Paragraph IV challenges target commercially profitable drugs, they undermine this cross-subsidy. In this manner, a challenge to one patented drug may also undermine another drug with an uncontested patent. From this perspective, the social value of a particular patent, even one subject to a Paragraph IV challenge, should be judged by the social value of the portfolio of patents held by the same pioneer drug company.

To be clear, amici do not take the position that reverse payment settlements always benefit consumers. But the evidence does suggest that it is premature—if not incorrect—to conclude that reverse payment settlements are so likely to harm

consumers that they should be presumptively illegal. That is so even if—as Petitioner contends—reverse payment settlements extend the duration of the defendant's patent or protect a patent that might lose in litigation.

Furthermore, it is unclear that Petitioner's proposed rule would benefit consumers even under its own logic. Assume, for the sake of argument, that Petitioner is correct that reverse payment settlements extend the expected duration of a pioneer drug company's challenged patent, harming consumers. By Petitioner's logic, it is still also the case that generic drug companies expect they would financially benefit from reverse payment settlements more than from litigating Paragraph IV challenges to judgment. Otherwise these generics—like the pioneer drug companies—would not have settled.

This implies that declaring reverse payment settlements presumptively illegal would reduce the financial return to generic drug companies from bringing Paragraph IV challenges. In other words, Petitioner's reasoning implies that, while a rule discouraging reverse payment settlements might benefit consumers after a Paragraph IV challenge is brought, it might also harm consumers by reducing the number of such challenges brought. Whether consumers would on balance be better or worse off is uncertain.

ARGUMENT

I. Petitioner Must Demonstrate that Reverse Payment Settlements Are So Unlikely to Benefit Consumers that this Court Should Judge Them Presumptively Illegal

Petitioner urges that reverse payment settlements be categorized as a presumptively illegal contract. Under this view, courts would treat a reverse payment settlement as illegal under antitrust law unless the defendant showed that the defendant's payments to a generic drug company under the settlement reflect either its litigation costs or consideration for unrelated property or services. FTC Br. at 17. Under Petitioner's view the antitrust defendant would not be allowed to defend a reverse payment settlement on the ground that its patent does not harm consumers. *Ibid.* In other words, Petitioner urges the Court to declare reverse payment settlements *per se* illegal except in narrow circumstances.

In order to prevail on such a bold claim, Petitioner must demonstrate to the Court that a particular set of reverse payment settlements—those that include payments from a defendant that exceed its litigation costs or that do not reflect consideration for unrelated property or services—are so likely to harm consumers that it is not worth the court's time and effort to determine whether a specific settlement in that set may still benefit consumers. *See, e.g., Broadcast Music, Inc. v. Columbia Broadcasting System*, 441 U.S. 1, 9 (1979). *See also California Dental Ass'n*, 526 U.S. at 770 (stating that a presumption of illegality under "quick look" rule of reason "carries the day when the great

likelihood of anticompetitive effects [on consumers] can be easily ascertained").

Petitioner's argument rests on certain economic theories about why drug patents judged valid by a court are economically desirable and why patents not affirmatively judged valid by a court harm consumers. Amici begin by describing these theories, without conceding they are correct. We will then highlight recent research from the field of health economics—specifically, research that focuses on the pharmaceutical drug market—that undermines these theories. This research has been neglected by Petitioner and by prior legal scholarship on reverse payment settlements. Amici will demonstrate that even the set of reverse payment settlements that involve reverse payments that exceed litigation costs or the value of unrelated property or services may not harm—and may even improve—consumer welfare. Therefore, these settlements should not be presumed illegal.

II. Petitioner's Argument Relies on a Contested Economic Theory About Patents and Patent Law

Petitioner's argument relies on the textbook economic model of patents to explain why patents judged valid may improve welfare, but patents whose validity has not yet been adjudicated do not. According to that model, patent law's 20-year limit on the duration of patents balances the costs and benefits of patents. Louis Kaplow, *The Patent-Antitrust Intersection: A Reappraisal*, 97 Harv. L. Rev. 1813, 1823, 1825-26 (1984). That 20-year limit gives the pioneer drug company holding a patent a 20-year period during which only the pioneer may

legally sell the patented drug in the U.S., *i.e.*, a monopoly that does not run afoul of antitrust laws. During this monopoly period, consumers pay a high monopoly price for the drug.

According to economic theory, a monopoly has anticompetitive effects on social welfare because this monopoly price stops certain consumers from purchasing the drug, consumers who would be willing to pay the marginal cost of the drug but not the higher monopoly price. This exclusion of consumers reduces the quantity of drug sales and thereby generates a loss to consumer welfare or surplus. FTC Br. at 22-23. Economists call this cost from patents, "static inefficiency." This cost is tolerated because the profits obtained by the pioneer drug companies rewards—and thereby incentivizes—a pioneer to incur the research and development costs to invent the patented drug. Kaplow, *Patent-Antitrust Intersection* at 1823. Economists call this benefit of patents, "dynamic efficiency."

While no one contends that the 20-year limit perfectly balances the static inefficiency and dynamic efficiency, it does achieve a certain balance that ought to be respected. Efforts to extend patent life beyond the limits set by patent law raise antitrust concerns because they limit competition in a manner that harms consumers. FTC Br. at 25-26.

According to Petitioner's view, patent law's balance between static inefficiency and dynamic efficiency applies only to patents that, if challenged, would be upheld in litigation. Such patents would meet patent law's standards of novelty, non-obviousness, and usefulness. The purpose of these

standards is to identify patents that have social value. The negative implication is that patents that are challenged and declared invalid by a court would not meet this standard and thus would not be socially valuable.

But Petitioner takes this implication further and suggests that patents that are challenged and settled—even though they are not declared invalid by a court—also lack social value. (Inexplicably, Petitioner does not extend the logic to patents that are not challenged, but if they were, would be declared invalid.) Thus Petitioner suggests that patents involved in reverse payment settlements generate static inefficiency, but no dynamic efficiency. FTC Br. at 18; Br. for the States of New York et al. as Amici Curiae in Support of Petitioner at 7-8; Br. Amici Curiae of 118 Law, Economics, and Business Professors and the American Institute in Support of Petitioners at 8, 20. Under Petitioner's legal theory, there is no value to incentivizing the creation of drugs covered by patents involved in reverse payment settlements.

The reason why Petitioner condemns reverse settlements is that the first generic to file a Paragraph IV challenge and a pioneer drug company holding the challenged patent can collude to hurt the consumer. According to basic market economics, the pioneer's monopoly profits (if its patent were left in place) are greater than the duopoly profits that the pioneer and first generic each get during the period of exclusivity (if the patent were invalidated). The pioneer can offer the first generic a part of this wedge to settle its challenge in the pioneer's favor. This side payment—called a "reverse payment"—

could increase the period of time during which the pioneer retains its profits. FTC Br. at 16 and 21. (Petitioner does not claim that reverse payment settlements extend a patent past the 20 years allowed by patent law. There is no theory or evidence to suggest reverse payment settlements accomplish that. Moreover, the Eleventh Circuit's scope-of-the-patents test would not allow such an extension. Pet. App. 28a.)

In order for Petitioner to show that it is correct that reverse payment settlements should be presumptively illegal under antitrust law, it must demonstrate its theory of patents applies to drug patents. If drug patents—whether involved in a reverse payment settlement or not—impose little or no static inefficiency, or if longer patent terms—even if secured by reverse settlements—do not on balance harm consumers at the expense of consumers, then reverse payment settlements may fall in the category of contracts that restrain trade but ought not and are not condemned by the Sherman Act and the FTC Act. If even patents covered by reverse payment settlements are valuable for dynamic efficiency, as Petitioner admits is the case for patents that are not challenged or that are litigated and upheld, then antitrust law should not label reverse payment settlements presumptively illegal.

A. Petitioner Overestimates the Cost of Drug Patents to Consumers

Courts must be "attuned to the particular structure and circumstances of the industry at issue" when applying antitrust law. *Trinko*, 540 U.S. at 411 (2004); FTC Br. at 30. The appropriate antitrust rule for an industry must "recognize and reflect the

distinctive economic and legal setting of the regulated industry to which it applies." *Trinko*, 540 U.S. at 411. The strict treatment of reverse payment settlements urged by Petitioner does not satisfy this requirement. It employs a conventional theory of patents that does not make any allowance for how pharmaceutical innovation takes place, the role of patents in the innovative process, and the structure of market competition for drug innovation and drug sales. As a consequence, it overestimates the cost of drug patents to consumers.

1. Empirical evidence suggests drug patents do not harm consumers by denying them access to drugs

A critical assumption of Petitioner's economic theory of patents is that it harms consumers by denying them access to patented products. Recent research in health economics suggests, however, that the monopoly conferred by a drug patent, whether that patent is associated with a reverse payment settlement or not, may not price any consumer out of the market.

The conventional economic model of patents to which Petitioner subscribes asserts that the patent holder, by virtue of its monopoly, is able to charge a high monopoly price for its drug that exceeds the price that would be charged if the drug were produced by a number of competing, generic drug companies. According to economic theory, the primary harm from patents is that this monopoly price would exclude a certain class of consumers from the market, specifically, consumers who value the patented drug more than the competitive price of the drug but not as much as the monopoly price of

the drug. Economists call this exclusion "deadweight loss" or static inefficiency. Kenneth Arrow, *Economic Welfare and the Allocation of Resources for Invention*, in National Bureau of Economic Research, The rate and direction of inventive activity: Economic and social factors, 609, 617 (1962).

The details of this conventional patent model, specifically its understanding of the harm from a monopoly, are illustrated in Figure 1 on the following page. The diagonal curve depicts consumer "demand" for the patent holder's product. The lower is the price charged for the product, the more consumers will demand of that product.

The monopoly conferred by a patent allows the patent holder to choose whichever price it wants to charge consumers for its product. If the patent holder chooses a price equal to the incremental cost of manufacturing an additional unit of the patented product, *i.e.*, equal to its "marginal cost", it would earn no profits. The revenue for each unit sold would just cover the cost of manufacturing each unit sold. There is, however, a higher price, described in the figure as the "monopoly price" that would earn the patent holder greater profits. At this higher price, the demand curve reveals that consumers would not purchase very much of the product, only the "monopoly quantity". Because the price is higher than the patent holder's marginal cost, however, the patent holder will earn a profit on each unit it sells. The aggregate profit the patent holder earns is equal to the quantity it sells multiplied by the profit it makes on each unit, *i.e.*, the shaded area labeled "monopoly profit."

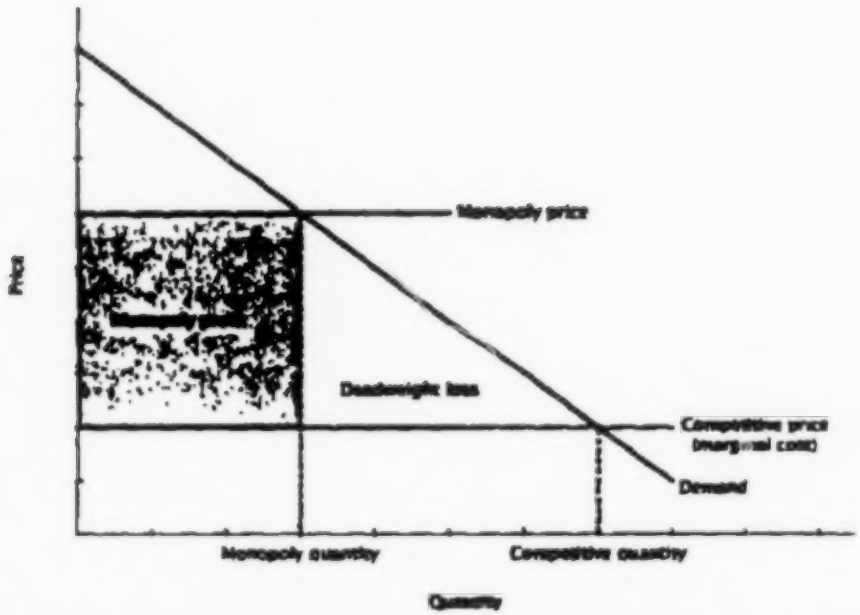


Figure 1. Illustration of the harm to consumers from monopoly pricing under the conventional model of patents.

If the patent holder's monopoly were removed, competitors could enter the market. Competition would drive the price of the product down to marginal cost. If one competitor tried to charge its customers more than marginal cost, another competitor could steal the first competitor's customers by offering a lower price, specifically its marginal cost, and still break even. This potential discourages competitors from charging anything other than marginal cost. Therefore, the figure labels marginal cost the "competitive price." At this price, consumers demand a high quantity of products, specifically "competitive quantity."

According to the conventional model of patents, the primary harm to consumers from a patent is that consumers are able to purchase more of the product in the absence of a patent than in the presence of a

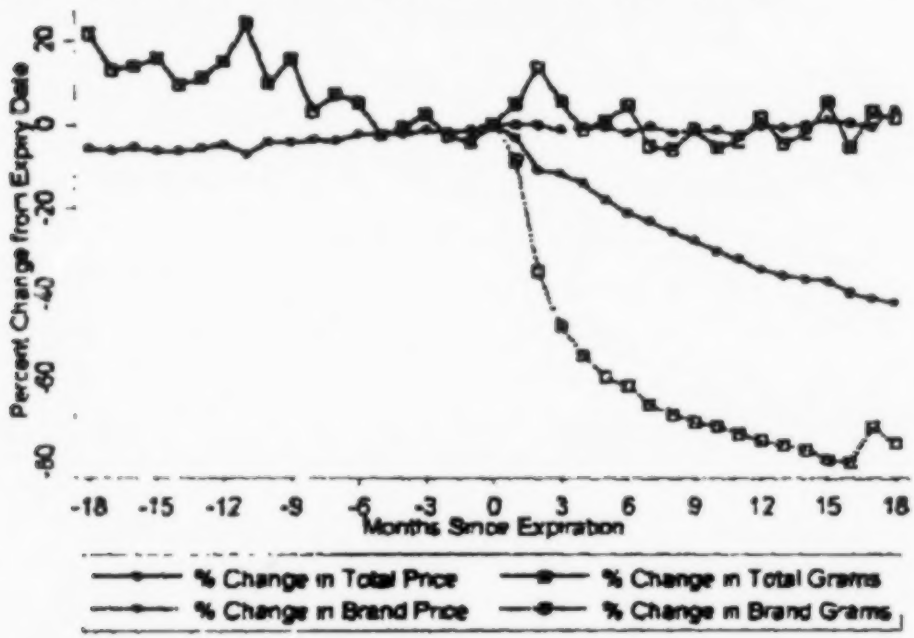
patent. The additional amount they are able to purchase is the difference between the competitive quantity and the monopoly quantity. The value to consumers of being able to purchase this additional amount is how much each unit is valued by consumers, *i.e.*, consumers' demand for each unit at that quantity, minus the cost of manufacturing each unit, *i.e.*, the marginal cost at that quantity. Since the demand curve is diagonal, the total loss suffered by consumers is the triangle labeled "deadweight loss."

An important feature of this consumer loss is that it is proportional to the difference between the amount of the product sold when it is under patent—the monopoly quantity—and the amount of the product sold when it is not under patent, the competitive quantity. That difference is the base of the deadweight loss triangle. If the difference is large there is a lot of harm to consumers. If the difference is zero, then there may be no harm to consumers.

The key prediction of the conventional model of patents is that, when a drug goes off patent, generic companies should enter, prices should fall, and—importantly—the quantity of drugs sold should rise. This prediction is what generates a difference between the monopoly quantity (under patent) and the competitive quantity (off patent), the difference that in turn determines deadweight loss.

This prediction is contradicted, however, by recent empirical data from pharmaceutical markets. While average drug prices certainly fall after patent expiration, overall drug sales do not rise. Darius Lakdawalla and Tomas Philipson, *Intellectual*

Property and Marketing, J. Law & Econ. (forthcoming 2013) (available at http://www.nber.org/papers/w12577); Frank R. Lichtenberg and Gautier Duflos, *The Effect of Patent Expiration on U.S. Drug Prices, Marketing, and Utilization by the Public*, 11 Med. Progress Rep. at 7 (2009) (Figure 6) (available at http://www.manhattan-institute.org/pdf/mpr_11.pdf); Ernst R. Berndt, Margaret K. Kyle, and Davina C. Ling, *The Long Shadow of Patent Expiration: Generic Entry and Rx-to-OTC Switches*, in Robert C. Feenstra and Matthew D. Shapiro, eds., Scanner Data and Price Indexes 229, 249-52 (2003) (available at http://www.nber.org/chapters/c9737.pdf).



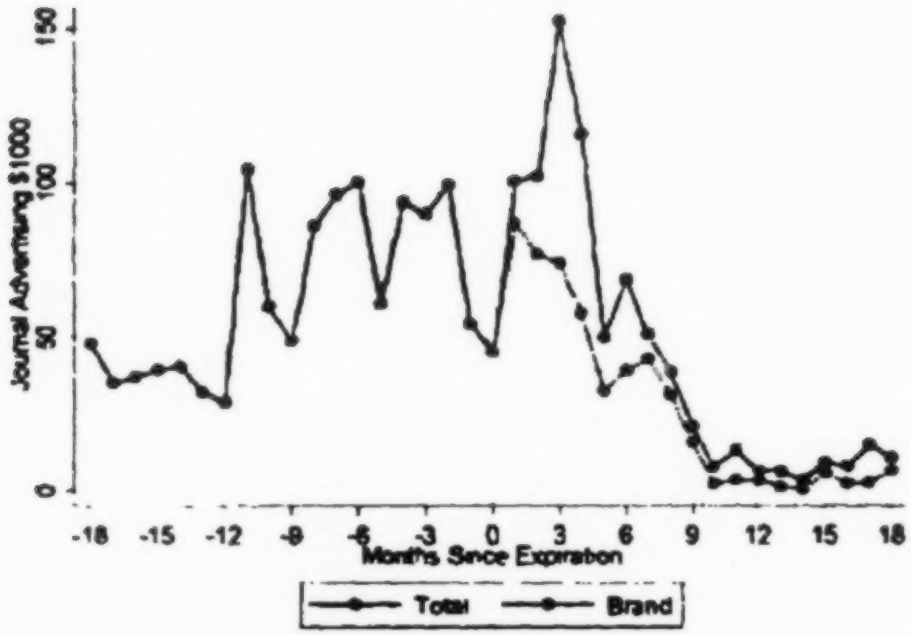
Source IMS Generic Spectra database Graph shows the percent change between the month of patent expiration and the month shown on the x-axis In all cases price is per gram

Figure 2. Drug quantity does not rise after patent expiration. Source: Lakdawalla and Philipson, *Intellectual Property and Marketing* (Figure 5).

This remarkable finding is depicted in Figure 2. After patent expiration (the 0 point on the x-axis), the pioneer drug company's price ("% Change in Brand Price") does not change but due to the entry of low price generics, the average price falls ("% Change in Total Price"). As a result, the pioneer drug company's sales ("% Change in Brand Grams") fall. What is surprising is that total sales including sales by the generics ("% Change in Total Grams") do not rise relative to pre-expiration levels.

The finding that drug sales do not increase after a drug goes generic suggests that patents do not deny consumers access to drugs. The finding does not distinguish between patents associated and not associated with settlements. From this one may conclude that there may be no deadweight loss or static inefficiency from patents in drug markets—even patents subject to reverse payment settlements—and the conventional model of patents may not apply to drug markets. Lichtenberg and Duflos, *Effect of Patent Expiration* at 12 ("[O]ur findings imply that, in practice, weaker (or shorter) patent protection would not increase Americans' access to prescription drugs").

A natural question is why drug quantity does not rise after patent expiration. One need not answer this question to conclude that there may be no static inefficiency from drug patents, but the answer does illuminate the gap between legal thinking about reverse payment settlements and health economic thinking about such settlements. The literature offers two possible explanations for why drug sales do not rise after patent expiration.



Source: IMS Generic Spectra database. Graph shows journal advertisement spending for the average molecule and the average branded molecule.

Figure 3. Advertising falls after patent expiration. Source: Lakdawalla and Philipson, *Intellectual Property and Marketing* (Figure 8).

The simplest explanation is that pioneer drug companies advertise their drugs and this advertisement raises sales. *See* Lichtenberg and Duflos, *Effect of Patent Expiration* at 6, 9, 12. As a result, even at monopoly prices, patients consume the same amount of drugs as they would at competitive prices. When patents expire, pioneer drug companies stop advertising because they do not fully appropriate the benefits of the ads, which increase both pioneer and generic sales. The decline in pioneer or "Brand" drug advertising is depicted in Figure 3. This decline in advertising offsets the increased consumption due to the price decline after patent expiration.

A second explanation for why drug patents may not prevent consumers from purchasing a drug is that consumers do not face the monopoly price of patented drugs. Most consumers do not pay for drugs out of pocket. Instead they have health insurance that covers the cost of drugs. Health insurance does not directly charge consumers the full price of drugs; rather it charges a copay, *e.g.*, $10 per prescription filled. This copay is not far from the competitive price of drugs. As a result, health insurance permits consumers to purchase the same amount of a patented drug as they would if it were not patented but sold at a competitive price by generic drug companies. Darius Lakdawalla and Neeraj Sood, *Innovation and the welfare effects of public drug insurance*, 93 J. Pub. Econ. 541, 541, 546 (2009); Darius Lakdawalla and Neeraj Sood, *Health insurance as a two-part pricing contract*, National Bureau of Economic Research Working Paper 12681 at 1-2 (2006) (available at http://www.nber.org/papers/w12681); Darius Lakdawalla and Neeraj Sood, *Health insurance as a two-part pricing contract*, Unpublished manuscript (2012).

Table 1 on the following page illustrates this point. It shows that for drugs whose sales are largely to consumers who have health insurance (third row, "75th percentile" insurance penetration), patent expiration is associated with no increase in drug quantity. For drugs whose sales are largely to consumers not well covered by insurance (first row, "25th percentile" insurance penetration), there is an increase in drug quantity after patent expiration.

Table 1. Patent expiration raises quantity only for drugs that are not well-insured. (Bold numbers indicate significantly different from zero.) Source: Lakdawalla and Sood, *Health insurance as a two-part pricing contract* (2012) at 4, 23.

Insurance Penetration Percentile	Insurer Share of Spending	Effect of Patent Expiration On: Quantity	Branded Revenue
25th percentile	41%	**+11%**	**-22%**
Median	57%	**+5.3%**	**-30%**
75th percentile	78%	-1.9%	**-40%**

Admittedly not all consumers currently have health insurance and so may not be protected against high drug prices by that insurance. Going forward, however, nearly all American will have health insurance. The 2010 Patient Protection and Affordable Care Act imposes an individual mandate that requires nearly everyone to buy health insurance. 26 U.S.C. § 5000A. Moreover, it provides most American households making less than $90,000 additional tax breaks to purchase insurance, 42 U.S.C. § 18081, or provides them government insurance by 2014, 42 U.S.C. §1396a(a)(10)(A)(i)(VIII). As a result, very shortly nearly all drug sales will be to consumers with insurance coverage.

Remarkably, health insurance not only lowers the price that consumers pay for patented drugs, it does so without necessarily lowering the price that pioneer drug companies receive for patented drugs. The insurance company can pay the pioneer a monopoly price and at the same time charge the consumer a near-competitive price for the drug. The reason is that health insurance is a two-part pricing scheme much like that used at amusement parks, where one pays a large up-front fee to enter the park but then gets tickets for rides in the park at a relatively low cost.

With health insurance, the consumer is charged a large entry price (the premium) for the right to buy individual units of drugs at a low marginal price (the copay). Lakdawalla and Sood, *Health insurance as a two-part pricing contract* (2012) at 1-2. This decoupling of the price of drugs that consumers face from the price of drugs that pioneer drug companies receive eliminates the tradeoff between dynamic efficiency and static inefficiency that is at the heart of the conventional model of patents and that plagues patents in non-pharmaceutical markets. *Id.* at 2 ("[M]onopolies in health care—whether due to patents, limited market size, or historical factors—may have smaller or even no deadweight costs in the goods market.").

A natural concern with how health insurance addresses the deadweight loss from patents in pharmaceutical markets is that such insurance merely transplants that loss to other markets, specifically, the health insurance market. If consumers consume a competitive quantity of patented drugs, but the insurer pays monopoly

prices for those drugs, surely that will increase health insurance premiums. Will the resulting increase in premium not reduce insurance consumption?

There is certainly some increase in the price of health insurance premiums due to drug patents. But this increase is likely to be nominal. Nearly 70% of all drug sales are sales of generic drugs. C. Scott Hemphill and Bhavan N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. Emp. Legal Stud. 613, 614 (2011). The prices of generic drugs are not affected by reverse settlements. Overall drug expenditures, including both branded and generic drugs, are roughly 10% of overall health expenditures. Therefore, drugs costs are a small driver of health insurance premiums. U.S. Census Bureau, Statistical Abstract of the United States: 2012 at 102 (Table 136). Most important, only a small fraction of branded drugs are involved in reverse payment settlements. Thus, reverse settlements have a minor impact even on the price of branded drugs.

Moreover, there are two reasons to think that any increase in premiums due to reverse payment settlements will not stop consumers from purchasing health insurance, the critical test of static inefficiency in that market.

First, the U.S. tax code subsidizes the purchase of employer-sponsored health insurance. This subsidy reduces the price that consumers face for insurance and thus the extent to which drug patents reduce consumption of insurance. Jonathan Gruber and Michael Lettau, *How elastic is the firm's demand for health insurance?* 88 J. Pub. Econ. 1273, 1274

(2004). Not surprisingly, a survey of the health economics literature reveals that "demand for health insurance is, in general, price inelastic." Su Liu and Deborah Chollet, *Price and Income Elasticity of the Demand for Health Insurance and Health Care Services: A Critical Review of the Literature*, Mathematic Policy Research Ref. No. 6203-042 at ix (2006) (available at http://www.mathematica-mpr.com/publications/pdfs/ priceincome.pdf).

Second, the Affordable Care Act includes a mandate requiring nearly all individuals to buy insurance. 26 U.S.C. § 5000A. To try to ease the burden of that mandate, the Act provides premium tax credits to individuals below 400% of the federal poverty level. The Act also expands Medicaid coverage for individuals too poor to afford health insurance. In this manner, the Affordable Care Act mandate, combined with its tax and Medicaid benefits, reduces—and perhaps eliminates—the possibility of an increase in the pool of uninsured due to reverse payment settlements. Therefore, whatever its other flaws or merits, one positive side effect of the Affordable Care Act is that it may mitigate the static inefficiency from drug patents by way of health insurance.

Admittedly, the tax subsidy for the purchase of health insurance and the Affordable Care Act's new premium tax credits and Medicaid expansion may increase government expenditures on health care. But for the same reasons that reverse settlements are likely to have only nominal effects on insurance premiums, they are likely to have only nominal effects on government expenditures. Moreover, the effects on government expenditures are smaller since

the government shares only a portion of the cost of health insurance premiums. In any case, even if there were some consumers harmed by the nominal increase in insurance premiums or government expenditures due to reverse settlements, their losses would likely be offset by the benefits consumers obtain from the new drugs developed by virtue of reverse payment settlements.

To summarize, recent health economics research suggests that drug patents do not reduce consumers' access to drugs or insurance, the key measure of deadweight loss or harm to consumers according to the conventional model of patents. This conclusion does not hinge on whether the drug is associated with a reverse payment settlement. Thus, even drug patents subject to reverse payment settlements may not harm consumers, a critical link in Petitioner's argument that such settlements should be help presumptively illegal.

2. Reverse payment settlements may not help producers at the expense of consumers

Implicit in Petitioner's economic model of patents is the idea that, if the patent holder's monopoly were ended, the patent holder's monopoly profits would accrue to consumers. Using this logic, Petitioner suggests that reverse payment settlements, by extending the expected duration of a pioneer drug company's patent, increases the resulting pioneer drug company's profits at the expense of consumers. FTC Br. at 16 and 21. While amici do not agree with Petitioner that reverse payment settlements necessarily extend the expected duration of a drug

patent, we do not think reverse payment settlements would harm consumers even if they did.

First, the pioneer drug company's profits during the patent period overstate producer welfare from the patent. Second, and more importantly, because pioneer drug companies finance innovation with retained earnings, profits from a patented drug sold to existing consumers are used to fund research and development into drugs that will benefit future consumers. Therefore, the duration of drug patents trades off the welfare of today's consumers with the welfare of future consumers. It does not, as the conventional theory of monopoly suggest, tradeoff the welfare of existing consumers and the welfare of producers. Petitioner fails to explain why antitrust law should take a strong stand in a battle between current and future consumers, as Petitioner's position on reverse payment settlements requires.

The profits that the pioneer drug company makes while its drug is under patent—including the additional period of exclusivity afforded by a reverse payment settlement—overstate the producer welfare obtained from a patent. These profits ignore the patent race that preceded the award of that patent. As Judge Posner observed long ago, when the government offers a monopoly such as a patent, firms will expend resources equal to expected monopoly rents to obtain that monopoly. Richard A. Posner, *The Social Costs of Monopoly and Regulation*. 83 J. Pol. Econ. 807, 807 (1975).

In the context of patents, the resources expended are R&D spending. Economists call the competition to obtain a patent a patent race. If the race to invent a given drug is competitive, *i.e.*, involves more than

one competitor, the total R&D expenditures across all the firms that compete in a race will dissipate the expected profits entering the race. Glenn Loury, *Market Structure and Innovation*, 93 Q. J. Econ. 395, 406-407 (1979).

The implication is that, notwithstanding the fact that some company will win and be observed earning positive profits during the patent period, in expectation the firms in the race may collectively make zero (or perhaps negative) expected profits. Moreover, even if the patent period were extended by a reverse payment settlement, firms that race for a patent will simply dissipate any additional prospective profits by increasing their R&D expenditures to obtain that patent. Thus, reverse payment settlements may not raise producer welfare.

An important implication of how patent races work is that Petitioner's choice of market for conducting its market exclusion analysis is incorrect. Petitioner asks the Court to examine exclusion in the market for a drug *once it is patented*. It admits that market exclusion (and profits) afforded by a valid patent is legally protected from antitrust scrutiny by patent law. Petitioner argues that market exclusion afforded by a patent covered by a reverse payment settlement is not protected from antitrust scrutiny because such settlements potentially extend the duration of patents that might have been judged in valid at trial. FTC Br. at 16 and 21.

But the fact that patent races may dissipate the profits obtained from a patent—whether that patent is involved in a reverse payment settlements or

not—suggests that the profits obtained from a patent is not truly producer welfare and the market for a drug once it is patented is the wrong market to search for exclusion. The correct market is the market for a drug patent, *i.e.*, the race for a patent. If that race is not competitive, then the ultimate patent holder's profits are evidence of actual producer welfare. But if the race is competitive, then profits from a patent, even one extended by a reverse payment settlement, are not evidence of producer welfare.

One piece of empirical evidence suggesting that the market for drug patents is competitive is that pioneer drug companies do not appear to make a supra-competitive return on assets even after accounting for the additional profits they obtain from reverse payment settlements. When calculating a company's return on assets, one must normalize for risk, especially scientific and regulatory risk involved in a patent race. Once that is done, the rate of return for pharmaceutical firms is only 2-3% higher than non-pharmaceutical companies. U.S. Congress, Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks and Rewards at 23*, OTA-H-522 (1993).

Other estimates suggest even worse performance, with pharmaceutical company returns only one-half percent above their cost of capital. Henry Grabowski, John M. Vernon, Joseph DiMasi, *Returns on research and development for 1990s new drug introductions*, 20 PharmacoEconomics 16 (2002). *See also* G.P. Pisano, *Science Business: The Promise, the Reality, and the Future of Biotech* 112-118 (2006) (finding negative profits in bio-

pharmaceutical companies). These data "tend[] to reduce substantially, if not to eliminate altogether, the inference that pharmaceutical companies are on average achieving supranormal profit returns." F.M. Scherer, *Chapter 12 - Pharmaceutical Innovation*, in H. H. Bronwyn & R. Nathan, eds., 1 Handbook of the Economics of Innovation 539, 564 (2010).

Not only might Petitioner overestimate the producer welfare that pioneer drug companies obtain from reverse payment settlements, Petitioner does not appear to take into account that the manner in which drug companies finance R&D expenditures determines how reverse payment settlements affect consumer welfare. Specifically, pioneer drug companies' use of retained earnings to finance R&D implies that reverse payment settlements may not convert consumer welfare into producer welfare. Rather, reverse payment settlements may convert the welfare of existing consumers—who provide retained earning—into welfare for future consumers, who benefit from the R&D financed by the retained earnings.

Drug companies tend to use profits from one patented drug to finance R&D for future drugs. They do not appear to rely very much on external financing, perhaps because it is hard to convince banks and outside investors that an as-yet-undeveloped drug will be clinically successful. Uwe Reinhardt, *Perspectives on The Pharmaceutical Industry*, 20 Health Aff. 136, 142 (2001). Because drug patents have such variable profits, drug companies also typically hold a portfolio of drugs to ensure a relatively stable flow of revenue to finance

R&D for future products. OTA, *Pharmaceutical R&D* at 8.

This reliance on retained profits for financing means that, at any point in time, a drug company's profits from patents on existing drugs sold to existing consumers are applied to R&D expenditures for future drugs sold to future consumers. F.M. Scherer, *The Link Between Gross Profitability And Pharmaceutical R&D Spending*, 20 Health Aff. 216 (2001). And this holds whether the profits are attributable to a patent covered by a reverse payment settlement or not. Figure 4 provides evidence for this. It shows that R&D expenditures track the gross margins of pioneer drug companies over time.

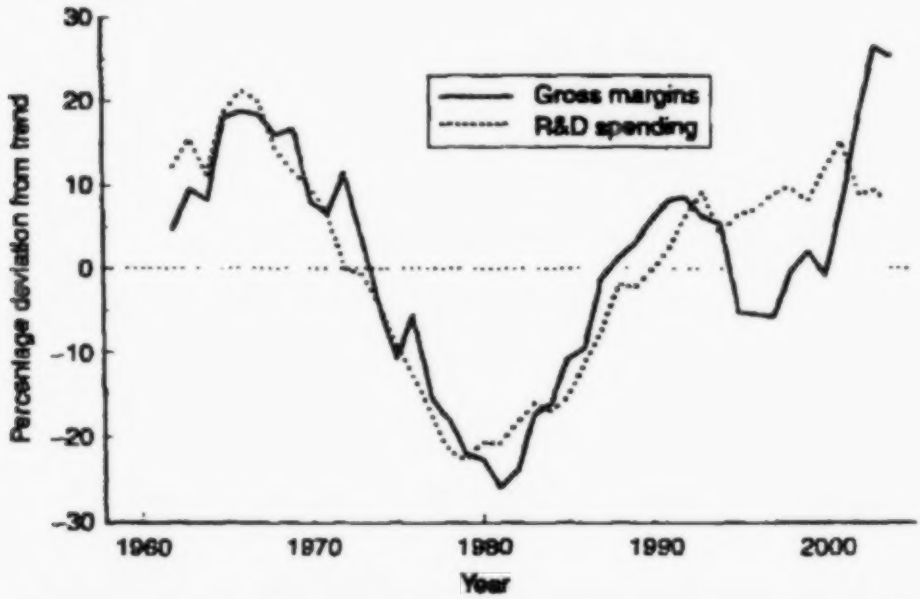


Figure 4. Trend-adjusted changes in pharmaceutical company margins and R&D spending. Source: Scherer, *Pharmaceutical Innovation* at 563 (Figure 5).

From this perspective, attempts to reduce patent duration—*e.g.*, by barring reverse payment settlements—are really attempts to shift consumer welfare from future consumers, the beneficiaries of current R&D expenditures, to current consumers. Once patent duration is understood to be a tradeoff between current and future consumers, it is not at all obvious what position antitrust law should take in the matter. Certainly, the economics of pharmaceuticals provide many reasons to doubt the claim that extending a drug patent, even one associated with a reverse payment settlement, is likely to harm consumers.

B. Petitioner Underestimates the Benefits Of Drug Patents To Consumers

Petitioner contends that a pioneer drug company is likely to enjoy a longer period of exclusivity for a patent if the litigation is settled than if the patent's validity were litigated to judgment.

Implicit in Petitioner's antitrust claim, which must make reference to the loss of consumer welfare from a patent, are two assumptions. First, the standards used to judge whether a patent is valid under patent law discriminates between those innovations that promote consumer welfare—and should enjoy a 20-year patent life—from those that do not and should not enjoy any further patent protection. Second, patents that are not actually held invalid by a court but are involved in a settlement also do not promote consumer welfare.

Amici agree with Respondent Solvay Pharmaceuticals that a reverse payment settlement does not imply that the associated patent would have been found invalid by a court, Br. for Resp. Solvay

Pharm. at 30. That undermines the second assumption. We go further and question the first assumption as well.

If the pioneer drug company's patent were litigated to judgment, then the patent's validity would be judged by the traditional patent standards of non-obviousness, novelty, and utility. These standards may measure the social value of non-drug patents, but they fail to capture the full social value from a drug patent.

First, the traditional standards for patent validity do not appreciate that all drug patents—whether valid or not—are necessary to compensate drug companies for conducting clinical trials. Moreover, clinical trials of a drug are socially valuable even if the patent covering that drug is associated with a reverse payment settlement.

Second, profits from a drug patent—even if the patent is involved in a reverse payment settlement—sustain research on a large number of other drugs, the patents on which may never be challenged or would be held valid if were challenged and litigated to judgment. This cross-subsidization implies that antitrust law should judge the consumer welfare created by a pioneer drug company by the consumer welfare from its portfolio of patents and not just from any individual patent it holds. Petitioner's position, implicitly applying traditional standards for patent validity to individual patents, fails to do that.

Our contention is not that traditional standards for judging patent validity must be perfect in order for antitrust law to rely on them in cases involving abuse of patents. Rather, our contention is that

there is a worse fit between patent validity standards and social value of innovation in the pharmaceutical industry than in other industries. As a result, in antitrust inquiries judging the value of pharmaceutical patents to consumers, courts should not rely as heavily as Petitioner contends on traditional patent validity standards and judgments upholding patent validity.

1. Drug patents associated with reverse payment settlements encourage socially valuable clinical trials

Nearly all drug patents encourage production of useful public goods, specifically information about whether a drug works. One reason is that, unlike patents for other products, a patent for a drug is typically obtained before research on the drug is completed. Specifically, drug companies obtain patents on molecules after lab and animal testing, but before clinical test, *i.e.*, testing on humans. Yet human testing is roughly half the cost of all drug R&D. Joseph A. DiMasi, Ronald W. Hansen and Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. Health Econ. 151 (2003).

Moreover, the results from clinical trials, which are made public as part of the drug approval process, are a public good. Once a drug is shown to be effective, generics would know whether it is effective and enter the market in the absence of a patent. If a company did not have a patent that could prevent that entry, it would never recoup the costs of conducting clinical trials. Anticipating that, it would not conduct trials in the first place.

A second feature that distinguishes drug R&D, specifically clinical trials, from R&D for other products is that clinical trials are socially valuable even if the patents covering a drug were associated with a reverse payment settlement. It is socially valuable to learn whether a drug is safe and effective and that value is positive whether the relevant patent is litigated to judgment and upheld or settled. Professor Roin notes that a large number of molecules in the public domain—either because they were not patentable or their patents expired—may be valuable but are untested and unexploited because no company can recoup the costs of doing research on them. Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 Texas L. Rev. 503, 505-506 (2008-2009).

Further evidence comes from the Orphan Drug Act, which rewards drug companies that demonstrate via trials that a molecule is safe and effective at treating an orphan disease—a disease that afflicts 200,000 individuals or less per year—with up to 7 years of market exclusivity, even if the molecule is already in the public domain. 21 U.S.C. § 360cc(a). The Orphan Drug Act is thought to have successfully increased the number of treatments for orphan diseases. *See, e.g.*, Wesley Yin, *Market Incentives and Pharmaceutical Innovation*, 27 J. Health Econ. 1060, 1073 (2008); Alan M. Garber, *Benefits Versus Profits: Has the Orphan Drug Act Gone Too Far?*, 5 Pharmacoeconomics 88, 91 (1994). If market exclusivity for drugs that are in the public domain have social value, so too does market exclusivity for drugs that are associated with reverse

payment settlements rather than litigated to judgment and upheld.

Admittedly, information that a drug works may be more valuable than knowing a drug does not work. But the manner in which generic drug companies select patents for Paragraph IV challenges suggests that reverse payment settlements largely cover drugs that work—thus drugs for which trials are particularly valuable. All Paragraph IV challenges are filed against drugs approved by the FDA, *i.e.*, those already found to be safe and effective. Moreover, Professors Hemphill and Sampat have demonstrated that sales are an important predictor of Paragraph IV challenges. Hemphill and Sampat, *When Do Generics Challenge Drug Patents* at 613, 630, 632. And sales tend to follow drugs that work well rather than drugs that do not work well. This should not be surprising: generics companies also care about profits. Drugs that give the greatest value from Hatch-Waxman's 180-day market exclusivity period for the first-filing generic are exactly those drugs that are most profitable to the pioneer drug company.

One criticism of this line of argument is that patents may reward drugs companies "too much" for trials, *i.e.*, give them more money than is required to get them to do trials on the drug in question. Average sales for drugs that are subject to Paragraph IV challenges are $200 million. Hemphill and Sampat, *When Do Generics Challenge Drug Patents* at 628 (Table 2). This amount is greater than the $100.4 million it takes on average to conduct the three phases of clinical trials required for drug approval by the FDA. DiMasi *et al.*, *The*

Price of Innovation at 165 (Table 4). Revenue must cover the cost of pre-clinical testing, but those costs are only $60.6 million, leaving $39 million in profits per challenged drug. *Id.* at 162 (Table 1).

But there are many drugs for which trials are conducted and the drug is not approved. Cost estimates that account for the fact that revenues from drugs that are approved must pay for trials for drugs not approved range from roughly $800 million to $2 billion per approved drug. *See* DiMasi *et al.*, *The Price of Innovation* at 166 (giving an estimate of $802 million per approved drug); Christopher P. Adams and Van Vu Brantner, *Spending on New Drug Development*, 19 Health Econ. 130, 131 (2010) (confirming the $802 million estimate); Christopher P. Adam and Van Vu Brantner, *Estimating the Cost of New Drug Development: Is It Really $802 Million?* 25 Health Aff. 420, 425-426 (2006) (finding that for some firms the costs may rise to $2.1 billion per approved drug and $1.1 billion for some diseases).

Likewise, there are many drugs that are approved, but the drug does not generate enough revenue to cover the costs of R&D for the drug. Cost estimates here are unknown. Because the median drug does not cover it cost of development, Henry G. Grabowski and John M. Vernon, *Returns to R&D on new drug introductions in the 1980s*, 13 J. Health Econ. 383, 399 (1994) (Figure 5), the estimated costs of developing a profitable drug could be double, or as high as $1.6 billion to $4 billion. From this perspective, the average revenues on drugs subject to Paragraph IV challenges do not seem excessive.

An outside check on whether drugs subject to Paragraph IV challenges make "excessive" profits is

to examine overall drug company profits. If the profits from drugs subject to Paragraph IV challenges were "too profitable," drug companies should be making supra-competitive profits across their portfolio. As amici previously pointed out above, the health economics literature suggests that drug companies barely cover their actual cost of capital. *Ibid.*

2. Patents associated with reverse payment settlements may sustain research on unchallenged and affirmatively valid patents

Drug companies typically conduct trials on a number of drugs and even sell multiple approved drugs on the market. Carrying a number of drugs reduces the variability of a drug company's profits. Scherer, *Pharmaceutical Innovation* at 559; F.M. Scherer and Dietmar Harhoff, *Technology policy for a world of skew-distributed outcomes*, 29 Research Policy 559, 564 (2000). This smoothing of profits reduces the cost of capital to a drug company. Investors demand a higher rate of return on more risky investments. Offering investors a portfolio of drugs offers lower risk investment than offering just one drug. Therefore, *ceteris paribus*, investors demand a lower return from a company with a portfolio of drugs than a company with an individual drug. As a result, holding portfolios of drugs enables drug companies to raise capital at a lower cost. OTA, *Pharmaceutical R&D* at 8.

Carrying a portfolio of drugs also allows drug companies to lower capital costs by partly self-financing investment in innovation. Raising capital for R&D is difficult because companies typically

have more information about the prospects of their R&D projects than lenders or investors. This asymmetry makes lenders and investors reluctant to offer capital except at high rates of return. Again, an alternative to paying those high rates is for the company to finance R&D through retained earnings. Holding a portfolio increases the odds that at least one drug generates positive profits that can be retained for financing purposes. Scherer, *Link Between Gross Profitability and Pharmaceutical R&D Spending* at 216.

Combining the fact that drug companies carry portfolios with the fact that, adjusting for risk, drug companies do not make substantially supra-competitive profits, one can infer that drug patents that generate high profits cross-subsidize R&D on unprofitable patents on approved drugs and also patents on unapproved drugs. Paragraph IV challenges place pressure on this financing system because they target drugs with high sales. *See* Hemphill and Sampat, *When Do Generics Challenge Drug Patents* at 615. The ability of a pioneer drug company and a first-filing generic to settle a Paragraph IV challenge substantially reduces the impact that such challenges have on the pioneer's financing of R&D.

Petitioner contends that patents associated with reverse payment settlements are relatively "weak" patents. FTC Br. 7, 44. Amici agree with Respondent Solvay Pharmaceuticals that it is difficult to identify which patents are "strong" or "weak." Resp. Br. at 28-30. Certainly sham patents cannot be enforced. But drugs involved in reverse settlements might have been held valid had the

matter been fully litigated. Moreover, this Court's precedents hold patents as presumed valid until held otherwise. Resp. Br. at 19.

Even if one were to assume for the sake of argument that it is possible to distinguish "weak" patents from "strong" or valid ones, the fact that patents associated with reverse payment settlements are "weak" does not negate the fact that they generate substantial sales. Otherwise they would not have been subjects to Paragraph IV challenges by generic companies. *See* Hemphill and Sampat, *When Do Generics Challenge Drug Patents* at 613, 630, 632. Because all profitable patents cross-subsidize unprofitable ones, whether or not they are "weak," declaring reverse settlements presumptively illegal undermines the manner in which pioneer drug companies finance R&D.

Admittedly, allowing what Petitioner calls "weak" patents into a drug company's portfolio reduces the overall "strength" of that portfolio. But the position taken by Petitioner is that reverse payment settlement should be presumptively illegal, *i.e.*, not even one "weak" drug patent should be tolerated under antitrust law. Such a stance rules out the possibility that a portfolio of drug may have some—but not all— "weak" patents, that the portfolio would not exist (or have as many "strong" patents) without the "weak" but profitable patents, and that the portfolio as a whole is socially valuable. This possibility counsels against a strong presumption against reverse payment settlements.

CONCLUSION

The Court should affirm the judgment of the court of appeals and reject Petitioner's proposed rule.

Respectfully Submitted,

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AMICUS CURIAE BRIEF

No. 12-416

In The
Supreme Court of the United States

FEDERAL TRADE COMMISSION,

Petitioner,

v.

ACTAVIS, INC. ET AL.,

Respondents.

On a Writ of Certiorari to The United States Court of Appeals for the Eleventh Circuit

BRIEF OF AMICUS CURIAE INTELLECTUAL PROPERTY OWNERS ASSOCIATION IN SUPPORT OF RESPONDENTS

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Sobel, Gerald, *Consideration of Patent Validity in Antitrust Cases Challenging Hatch-Waxman Act Settlements*, 20 FED. CIR. B.J. 47 (2010) 13

INTEREST OF *AMICUS CURIAE*

Intellectual Property Owners Association (IPO) is a trade association representing companies and individuals in all industries and fields of technology who own or are interested in U.S. intellectual property rights. IPO's membership includes more than 200 companies and a total of over 12,000 individuals who are involved in the association either through their companies or as inventor, author, executive, law firm, or attorney members. Founded in 1972, IPO represents the interests of all owners of intellectual property. IPO regularly represents the interests of its members before Congress and the USPTO and has filed *amicus curiae* briefs in this Court and other courts on significant issues of intellectual property law. The members of IPO's Board of Directors, which approved the filing of this brief, are listed in the Appendix.[1]

IPO submits this brief in support of Respondents in light of the importance of strong patent protection and the special role that patents play in encouraging pharmaceutical research and development.[2] IPO believes the presumption of illegality that Petitioner would attach to so-called reverse payment patent settlements would have a substantial negative

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[1] IPO procedures require approval of positions in briefs by a two-thirds majority of directors present and voting.

[2] No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae* or its counsel made a monetary contribution to its preparation or submission. The parties have consented in writing to the filing of this brief.

impact on innovation in the pharmaceutical industry and beyond.

SUMMARY OF ARGUMENT

Contrary to the position advanced by Petitioner and its *amici*, the issues in this case are fundamentally different from those in classic market division cases (*e.g.*, *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46 (1990)), where naked agreements among competitors are properly held to be *per se* violations of Section 1 of the Sherman Act. In such cases, the parties allocate markets without even an arguable basis for challenging each other's entry in the absence of a collusive agreement. Here, by contrast, a lawfully issued and presumptively valid patent would, until its expiration, bar generic firms from entering the market and competing with AndroGel® unless the patent were ruled either not valid or not infringed.

Central to this case—and to evaluating the agreements at issue—are the unique dynamics involved in the parties' efforts to settle expensive and time-consuming patent litigation on commercially reasonable terms that compromise the risk of unpredictable, erratic, or erroneous outcomes. Efforts to settle litigation of any kind usually involve mutuality of risk. Each party tries to assess a variety of factors that might affect that party's interests if the case should proceed to trial; both parties then try to find an agreeable exchange of increments of value that can offset one another and resolve the case without a trial.

The same is true of a patent infringement case, except that the opportunities for both misaligned risk assessments in settlement negotiations and erroneous outcomes at trial are often greater because

of the technical subject matter. Nonetheless, both sides in a typical patent case have something significant at risk if the case goes to trial. The infringer faces the possibility of substantial damages, maybe an injunction, and sometimes attorneys fees. The patent owner faces the risk of having a valuable property right being held invalid or substantially narrowed in scope, and often the further prospect of counterclaim liability. The settlement of such a case thus reflects the composite interaction of separate parties, each trying to predict and evaluate highly uncertain future events, and the mutual resolution of risk factors.

With Hatch-Waxman cases, however, this mutuality of risk is either missing entirely or is heavily shifted to favor the challenger of the patent. The Hatch-Waxman Act was designed to facilitate the entry of generic drugs into the market by giving a generic manufacturer a low-risk path for challenging the validity or coverage of an innovator's patent. The Act allows generic drug makers to trigger patent disputes without actually placing their products on the market, thus eliminating the likelihood of a damage award. The Act also rewards the first generic firm to challenge a patent associated with a particular drug by awarding 180 days of exclusivity following FDA approval and a successful patent challenge.

Data collected by the Federal Trade Commission show that generic drug makers have raced one another to challenge innovators' patents, and that they have compelling incentives to do so with little or no regard for the merits of those challenges. The heavily skewed risk profile of a Hatch-Waxman patent challenge essentially eliminates the normal

incidents of value that facilitate the settlement of other types of patent cases. In this judicial and regulatory construct, a transfer of value from the innovator to the generic manufacturer should not automatically—or even presumptively—trigger antitrust liability. Numerous courts and economists have found that, far from being "inherently suspect" as Petitioner would have it, such transfers of value are essential to facilitate settlement.

Simply put, there is no basis in law or logic to require the settling parties in a Hatch-Waxman case to overcome a presumption of illegality in order to justify a reverse payment settlement. To create such a requirement would negate the well-established statutory presumption of a patent's validity. Instead, the Court should hold that the objectives of the antitrust laws are met by asking whether the settlement unreasonably restrains trade outside the scope of the patent in question and allowing the parties to reach an arm's-length bargain where no such impact is apparent.

ARGUMENT

I. CONSUMERS BENEFIT FROM LEGAL STANDARDS THAT GIVE FULL FORCE TO PATENTS AND FACILITATE NEGOTIATED RESOLUTION OF PATENT LITIGATION

As a recent report published by the Department of Commerce acknowledges, "[t]he granting and protection of intellectual property rights is vital to promoting innovation and creativity and is an essential element of our free-enterprise, market-based system." Economics and Statistics Administration & United States Patent and

Trademark Office, United States Department of Commerce, *Intellectual Property and the U.S. Economy: Industries in Focus*, v (March 2012) (hereinafter *Commerce Department Report*), *available at* http://1.usa.gov/IkztGg. Clearly, innovation drives our national economy, and strong IP protection fuels that innovation.

A. Strong Patent Protection Serves As The Cornerstone For Innovation

Patents provide essential incentives for companies to invest in research and development and to assure the capital necessary to bring new products to market. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989) ("The federal patent system thus embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years."). As the government has explained:

> The investments necessary to develop IP are often quite substantial. Firms and individuals, in order to invest the necessary resources, need some assurance that they will benefit from and recover the costs of the creation of intellectual property.

Commerce Department Report at 1. The fundamental mechanisms of the patent system have worked effectively for over two centuries to foster new technologies and new industries on an unparalleled scale.

B. Patent Protection And A Strong Patent System Are Essential Predicates To Bringing New Medicines To Market

In terms of their impact on personal and public health, pharmaceutical innovations surely stand among the most important advances in recent history. According to two University of Chicago economists, "[o]ver the last half century, improvements in health have been as valuable as all other sources of economic growth combined." Kevin Murphy & Robert Topel, *Measuring the Gains from Medical Research: An Economic Approach*, 4 (2003).

Patent protection is particularly critical to pharmaceutical innovation, given the immense investments and significant time required to discover and obtain regulatory approval for new drugs and the comparative ease of copying after an innovator has made those investments. *See, e.g.*, Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575, 1616-17 (2003) ("The ratio of inventor cost to imitator cost, therefore, is quite large in the absence of effective patent protection. As a result, it is likely that innovation would drop substantially in the pharmaceutical industry in the absence of effective patent protection."); *see also* Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. Int'l Econ. L. 849, 851 (2002) ("Absent patent protection, . . . imitators could free ride on the innovator's FDA approval and duplicate the compound for a small fraction of the originator's costs.").

Winning FDA approval for a new drug takes, on average, 15 years and costs more than $1 billion. *See* Peter Hutt et al., *Food and Drug Law* 764 (3d ed. 2007); PhRMA, *Drug Discovery and Development*,

available at http://onphr.ma/fTUYTc (last visited Feb. 22, 2013).[3] This figure includes the costs of working with thousands of compounds that enter the drug development pipeline but ultimately never make it to market. For every 5,000 to 10,000 compounds that enter the pipeline, only five will ever progress to clinical studies in humans and only one will ultimately receive FDA approval. PhRMA, *Drug Discovery and Development: Understanding the R&D Process*, 2 (February 2007), *available at* http://bit.ly/12gRzn1. One economist has noted that "[w]ithout a well-structured system of patent protection, neither the research pharmaceutical industry nor the generic industry would be able to grow and prosper, as the rate of new product introductions and patent expirations would decline significantly." Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. Int'l Econ. L. at 853. Indeed, without patent protection, an estimated 65 percent of pharmaceutical products would never have been brought to market. Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 Mgmt. Sci., 173, 175 (1986).

C. The Ability To Settle Patent Litigation On Terms Acceptable To Both Parties Is A Crucial Component of Patent Enforcement

Pharmaceutical companies, like all patent owners, are entitled to assert their patents in court.

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[3] This figure likely underestimates the actual cost. A comparison of R&D budgets to the number of drugs major pharmaceutical companies launched over the last fifteen years yields average costs/successful launch of $3.6 billion to $11.8 billion. Matthew Herper, *The Truly Staggering Cost of Inventing New Drugs*, Forbes, (Feb. 10, 2012), *available at* http://onforb.es/zxOm33.

Just as the right to litigate is vital to realizing fully a patent's protective purpose, so too is the right to resolve that litigation through a negotiated settlement. "The general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits." *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1072 (11th Cir. 2005) (citations omitted).[4] Settlements resolve disputes with far less risk, time and expense than litigation imposes on the parties. They ease the burden on scarce judicial resources. And they provide certainty for all parties, allowing companies to focus on business interests rather than litigation disputes.

Petitioner pays lip service to the long-standing "public policy favoring settlement", yet gives virtually no weight to this policy in its analysis. Pet'r. Br. at 47. Instead, Petitioner asks the Court to adopt a rule that would raise substantial obstacles to settlement. Rather than enhancing competition from generic drugs, limiting settlement options could result in fewer patent challenges because generics will face greater risks challenging patents. Likewise, a rule that favors litigation to final judgment over settlement will also mean less generic competition because in recent years generic drug makers have lost more Hatch-Waxman trials than they have won.

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[4] *See also McDermott, Inc. v. AmClyde*, 511 U.S. 202, 215 (1994) ("public policy wisely encourages settlements"); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1333 (Fed. Cir. 2008) ("there is a long-standing policy in the law in favor of settlements"); Brett Dickey, et al., *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 Annals Health L. 367, 375-76 (2010) (describing benefits of patent settlements compared to litigation).

Petitioner's dismissive attitude toward settlements appears to be driven by a belief that patent owners are willing to settle litigation primarily because the patents in question are weak. *See* Pet'r. Br. at 44 (pointing to purported "empirical evidence concerning actual outcomes in litigated patent cases"); Brief of *Amicus Curiae* Knowledge Ecology International in Support of Petitioner at 17; Brief of Apotex, Inc. as *Amicus Curiae* Supporting Petitioner at 4. In reality, data gathered by PricewaterhouseCoopers shows that branded pharmaceutical companies won 50% of Hatch-Waxman cases, on average, between 2006 and 2011 (and won 56% and 53% of cases in 2010 and 2011 respectively). PricewaterhouseCoopers, 2012 Patent Litigation Study 28 (2012), *available at* http://pwc.to/SHzquB. Faced with the uncertainties inherent in litigation and a 50% probability of winning, it is no surprise that both parties often prefer to settle rather than litigate to final judgment. Petitioner's claim that generics win 75% of the cases that go to trial is based on old data that looks only to the 1992 to 2000 time period. *See* Pet'r. Br. at 6-7.

More fundamentally, differentiating a weak patent from a strong one is not something readily accomplished by looking retrospectively at litigation outcomes in other cases. The fundamental reality of patent litigation is that the process is highly unpredictable, even to experts, and is error prone. This means that the strongest of patents has a substantial chance of losing after a trial and appeal, just as the weakest of patents has a substantial chance of winning. This reality nullifies any

conclusions that one might discern from a summary of outcomes in a small number of cases.[5]

Finally, Petitioner's reasoning ignores the statutory directive that patents "shall be presumed valid." 35 U.S.C. § 282. This presumption of validity does not permit the classification of patents as either weak or strong. An issued patent is presumed valid until it is adjudicated otherwise. As this Court recently recognized, in the face of similar arguments in a different context, neither allegations of "bad" or "weak" patents nor purported flaws in the patent system justify adoption of a legal standard that ignores the Congressional intent of Section 282. *See Microsoft Corp. v. i4i Limited Partnership*, 131 S. Ct. 2238, 2251-52 (2011) (policy arguments concerning "bad" patents cannot override Congress' intent that the presumption of a patent's validity can be overcome only by clear and convincing evidence).

When the parties to a patent case can find common ground on which to settle the case, a rule forcing the case to trial will be counterproductive. The Hatch-Waxman Act was intended to give generic drug makers the incentive to challenge patents, which it clearly does. The Act was not intended as a surrogate for the reexamination of every patent subjected to its procedures.

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[5] In 2011, the FTC lost two out of three of its litigated merger challenges. *See* Federal Trade Commission and Department of Justice, *Hart-Scott-Rodino Annual Report Fiscal Year 2011*, at 16-17, available at http://1.usa.gov/YEHivl. But Petitioner would presumably agree that its 33% win rate in litigated cases does not suggest that it likewise had "weak" arguments in the nine merger cases it settled that year via consent decree.

II. THE HATCH-WAXMAN ACT CREATES INCENTIVES THAT FUEL WEAK CHALLENGES AND INVITE REVERSE PAYMENT SETTLEMENTS

Innovators who bring a new pharmaceutical product to market go through a time consuming and expensive process to secure FDA approval of a New Drug Application, or "NDA." In contrast, the Hatch-Waxman Act allows generic drug makers to use a radically less expensive and faster process, the Abbreviated New Drug Application, or "ANDA," essentially "piggy-backing on the brand's NDA." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012).[6] Firms pursuing this approach must show only that their generic product has the same active ingredients and is bioequivalent to a reference drug that previously has been approved. *Id.* Further, a company can seek approval from the FDA to market the generic drug before the expiration of a patent relating to the brand name drug by certifying that the patent in question is invalid or not infringed by the generic product (a "Paragraph IV certification"). 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

From the standpoint of the generic company, one of the most attractive features of the Hatch-Waxman Act is the ability to initiate a challenge to the patent without incurring any liability in doing so. Filing a Paragraph IV certification, in and of itself,

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[6] In contrast to the huge sums spent on bringing an innovator drug to market, the cost of preparing and filing an ANDA is about $1 million. Emily Morris, *The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act*, 22 Fordham Intell. Prop. Media & Ent. L.J. 245, 262 (2012).

constitutes an act of patent infringement, but in name only. 35 U.S.C. § 271(e)(2)(A). The patent holder does not sustain any damages, and the generic challenger is not required to bring products to market as a prerequisite to the challenge.[7] Normally, the generic drug maker's only risk in challenging a patent is that it will spend money on legal fees and FDA filings that it may not recover (or may recover only after patent expiration) if it loses the litigation. Further, the Hatch-Waxman Act grants 180 days of exclusivity to the first generic company to succeed in challenging an innovator's patents and win FDA approval for its product. 21 U.S.C. 355(j)(5)(B)(iv). Because the innovator's brand product rapidly loses substantial market share to the first generic that enters the market, a successful patent challenge often means enormous profits for the generic company.[8]

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[7] *See* Gerald Sobel, *Consideration of Patent Validity in Antitrust Cases Challenging Hatch-Waxman Act Settlements*, 20 FED. CIR. B.J. 47, 51 (2010) ("Unlike the usual patent case, there are ordinarily no damages claims against the generic because Hatch-Waxman forces the litigation to occur in the period prior to marketing by the generic. As a result, no sales or profits are lost by the patentee to the generic. While patent infringement suits are often settled by compromise of a damages claim, that vehicle is typically not available in Hatch-Waxman cases.").

[8] Data collected by the FTC show a generic drug maker predicting gross profits of $170 million in the first ten months following the launch of a generic version of a drug with $500 million in annual brand sales. Fed. Trade Comm'n, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact at 91 n.57 (Aug. 2011), *available at* http://1.usa.gov/oGSiIg (hereinafter *FTC Report*).

The result of this combination of factors is that the Hatch-Waxman Act creates a powerful incentive for generic drug makers to challenge patents even where the patent holder is highly likely to prevail in court. Under these circumstances, as explained in more detail below, it is no wonder that "reverse-payment" settlements are the "natural by-product of the Hatch-Waxman process." *Schering-Plough*, 402 F.3d at 1074 (internal quotation marks omitted).

A. Hatch-Waxman Creates An Incentive For Generic Drug Makers To Challenge Patents Even Where They Have Almost No Chance Of Success

The actual result of these "skewed" incentives under the Hatch-Waxman framework is stunning. Petitioner itself recently concluded that "for a drug with [annual] brand sales of $130 million, a generic that does not anticipate [authorized generic] competition will expect a patent challenge to be profitable if it has ***at least a 4 percent chance of winning*** . . . ."[9] FTC Report at iii n.7 (emphasis added). If there is an authorized generic, the challenger "would need [only] a 10 percent chance of winning to expect a patent challenge to be profitable." *Id.*

Even the eye-catching statistics in the FTC Report understate the magnitude of generic drug makers' skewed incentives. Only about three percent of dollar sales of branded drugs facing a first

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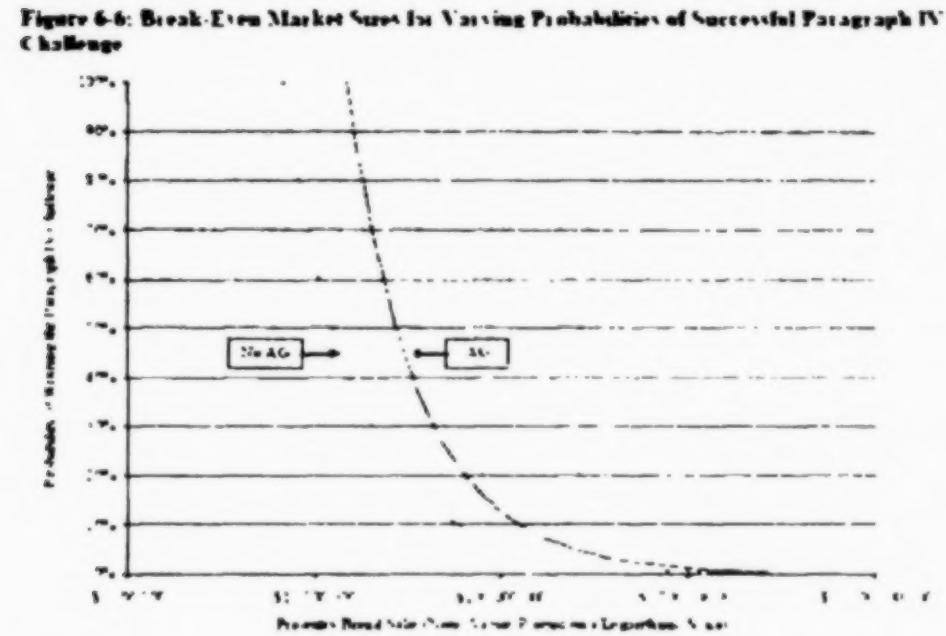
[9] "Authorized generic" or "AG" refers to a drug that is marketed by either the branded drug company or its licensee as a generic product under the innovator's NDA rather than under an ANDA. *See Mylan Pharm. v. FDA*, 454 F.3d 270, 273 (4th Cir. 2006).

generic challenge involve drugs whose annual sales are at or below $130 million. *Id.* at 115. The "break-even" likelihood of success required for a generic challenge falls dramatically as the level of sales increases. The following chart, taken from the FTC Report, shows that the likelihood of success required to justify a challenge to the patent covering a blockbuster drug is—literally—vanishingly small.



Id. at 118.

Specifically, for more than 90% of branded drug sales (measured in dollars), a generic challenger balancing upside gain under Hatch-Waxman against downside risk limited to litigation costs can justify the challenge if it believes it has at least a 1.3% chance of success. Kelly Smith & Jonathan Gleklen. *Generic Drugmakers Will Challenge Patents Even When They Have a 97% Chance of Losing: The FTC Report that K-Dur Ignored*, CPI Antitrust Chronicle, 2 (Sept. 2012), *available at* http://bit.ly/VMMTTS.

The FTC's own analysis thus shows that there are more likely to be challenges to drug patents than to other kinds of patents and that, when a blockbuster drug is involved, it is economically rational to challenge the patent even in the absence of grounds to believe the patent is infirm.[10] Indeed, in one case, the decision to pursue a generic version of a patented drug was made by the generic company's CEO based on historic sales levels, without consulting a patent lawyer and without review of the file history of the patents at issue. *Glaxo Grp. Ltd. v. Apotex, Inc.*, 268 F. Supp. 2d 1013, 1022-23 (N.D. Ill. 2003), *aff'd in part, rev'd in part*, 376 F. 3d 1339 (Fed. Cir. 2004). Moreover, incentives to challenge patents extend beyond the first generic filer; it is not unusual for blockbuster drugs to attract multiple generic challengers. *See* Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 Santa Clara Computer & High Tech. L.J. 489, 520-21 & n.177 ("Highly profitable drugs with tremendous therapeutic utility should and do generally attract multiple generic challengers."); Dickey et al., *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 Annals Health L. at 377 & n.59.

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[10] *See* Morris, *The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act*, 22 Fordham Intell. Prop. Media & Ent. L.J. at 262 ("In effect, the Hatch-Waxman Act actually makes pharmaceutical patents weaker than any other type of patent by making challenges to pharmaceutical patents easier and more attractive than for any other type of patent.").

B. Reverse Payments Are A Natural Response To The Hatch-Waxman Framework

Numerous courts and commentators have attributed the prevalence of "reverse payment" settlements in Hatch-Waxman litigation to this distorted litigation dynamic. *See, e.g., Schering-Plough*, 402 F.3d at 1074; *In re Ciprofloxacin*, 544 F.3d at 1333 n.11; Dickey et al., *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 Annals Health L. at 388-89; Kevin McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On "Probabilistic" Patent Rights and False Positives*, Antitrust 68, 69-70 (2003). As one court explained:

> [T]he Hatch-Waxman Amendments grant generic manufacturers standing to mount a validity challenge without incurring the cost of entry or risking enormous damages flowing from any possible infringement. Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude.

Schering-Plough, 402 F.3d at 1074 (citations omitted). In other words, reverse payments from the brand to the generic—even sizeable ones—should not be treated as unusual or inherently suspect.

Petitioner argues that there is nothing about the structure of the Hatch-Waxman Act that mandates "reverse-payment agreements as a natural response to the incentives that the Amendments create." Pet'r. Br. at 49. That argument is directly contrary to what the United States told this Court in its brief in an earlier case recommending against certiorari,

where the United States acknowledged that "[t]he resulting disparity in the litigants' respective risks may tend to increase the cost of settlement for a patent holder and make reverse payments more likely, even when the patent holder's legal claims are relatively strong." Brief for the United States as *Amicus Curiae* at 10, *Joblove v. Barr Labs.Inc.*, 551 U.S. 1144 (2007) (No. 06-830), *available at* http://1.usa.gov/XXiyhj. *See generally Schering-Plough Corp. v. FTC*, 402 F.3d at 1074-75 ("The Commission's inflexible compromise-without-payment theory neglects to understand that '[r]everse payments are a natural by-product of the Hatch-Waxman process.'") (quoting *In re Ciprofloxacin*, 261 F. Supp. 2d at 252 (E.D.N.Y. 2003)).

Petitioner argues that the increased leverage a generic manufacturer holds over the innovator in the Hatch-Waxman context need not result in a reverse payment, but could instead lead the generic manufacturer to negotiate for an earlier entry date. Pet'r. Br. at 50. This assertion fails to account for the difficulty encountered in settling many patent cases. Of course there may be situations where early entry might be sufficient to satisfy the generic challenger and secure a settlement in a specific case. On the other hand, the parties often have disparate views of the merits of a case, different risk profiles, and different priorities in terms of the litigation and settlement negotiations. In those situations, settlements can be difficult to achieve. *E.g.*, *Schering-Plough*, 402 F.3d at 1073 ("Schering presented experts who testified to the litigation truism that settlements are not always possible. Indeed, Schering's experts agreed that ancillary agreements may be the only avenue to settlement.");

Steven W. Day, *Leaving Room for Innovation: Rejecting the FTC's Stance Against Reverse Payments in Schering-Plough v. FTC*, 57 Case W. Res. L. Rev. 223, 250-55 (2006) (discussing "practical reasons" why an innovator and a generic firm may not be able to reach a settlement by agreeing solely on an earlier generic entry date).[11]

The fact is that a reverse payment (or other transfer of value) may facilitate a settlement in the Hatch-Waxman context when nothing else will, thus avoiding litigation costs and still providing for generic entry prior to patent expiration.

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[11] In 2007, the CEO of generic manufacturer Barr Pharmaceuticals testified before the Senate Judiciary Committee that the ability of parties to reach a settlement agreement that provides for some consideration in addition to generic entry prior to patent expiration can assist parties "to narrow the gap" that may exist based on the parties' evaluations of the case on its merits. Paying Off Generics to Prevent Competition with Brand Name Drugs: Should It Be Prohibited? Hearing before S. Comm. On the Judiciary. 110th Cong. 28 (2007) (Statement of Bruce L. Downey, Chairman and CEO, Barr Pharm., Inc.).

III. REVERSE PAYMENT SETTLEMENTS SHOULD NOT BE CONSIDERED PRESUMPTIVELY UNLAWFUL AND ARE NOT PROPERLY SUBJECT TO A "QUICK LOOK" ANALYSIS

A. Applying A Presumption Of Illegality To Settlements That Fall Within The Scope Of The Patent Claims Would Contravene Precedent And Petitioner's Previous Statements To The Court

Petitioner acknowledges that "it is well established that" patent settlement agreements "generally do not violate the antitrust laws." Pet'r. Br. at 26 (citing *Standard Oil Co. (Ind.) v. United States*, 283 U.S. 163, 171 (1931). This principle flows from the nature of the patent right itself and the fact that "the essence of a patent grant is the right to exclude others from profiting by the patented invention." *Dawson Chem. Co. v. Rohm and Haas Co.*, 448 U.S. 176, 215 (1980). If the patent owner has the statutory right to exclude others from activities within the scope of its claimed invention, there can be no adverse effect on competition in settling patent cases on terms that simply honor such proper exclusion. *E.g.*, *United States v. United Shoe Mach. Co.*, 247 U.S. 32, 57 (1918) ("[T]he right to exclude others from the use of the invention . . . . is not an offense against the Anti-Trust Act."); *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 24 (1997) (referencing "this Court's numerous holdings that it is the claim [of the patent] that defines the invention and . . . the limits of the patent monopoly").

Notwithstanding this right of a patent owner to exclude competitors from activities that would

infringe the claims of a patent, a right reaffirmed in multiple decisions of this Court over more than a century, Petitioner urges adoption of a rule under which *every* patent litigation settlement that does not permit immediate entry by the alleged infringer becomes suspect and subject to "antitrust analysis requir[ing] a nuanced examination of the specific terms" of the settlement. Pet'r. Br. at 27. This argument, as with much of Petitioner's position in this case, ignores the statutory presumption of validity and effectively assumes that any infringer that asserts the invalidity of a patent is likely to prevail, thereby benefiting consumers with lower prices. Petitioner does not explain how one would conduct the "nuanced examination" ostensibly required, except to say that the "likelihood that the patent holder would have prevailed" is irrelevant to that analysis. *Id.* at 54.

Petitioner would apply a particularly harsh rule to settlements involving a "reverse payment," arguing that such settlements should be viewed as "presumptively unlawful." *Id.* at 19. In so doing, the United States has abandoned the view, thrice-stated in briefs filed with this Court, that reverse payments are not presumptively unlawful. *See* Brief for the United States as *Amicus Curiae* at 9, *Andrx Pharms. Inc. v. Kroger, Co.*, 543 U.S. 939 (2004) (No. 03-779), *available at* http://1.usa.gov/Xf3qhd ("Reverse payments may have the salutary effect of facilitating efficient settlements that advance consumer welfare."); Brief for the United States as *Amicus Curiae* at 11, *Joblove v. Barr Labs. Inc.*, 551 U.S. 1144 (2007) (No. 06-830), *available at* http://1.usa.gov/XXiyhj ("[T]he public policy favoring settlements, and the right of a patent holder to exclude competition within the scope of its valid

patent, would be frustrated by adoption of a legal standard that subjected patent settlements involving reverse payments to automatic or near-automatic invalidation."); Brief for the United States as *Amicus Curiae* at 11, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No 05-273), *available at* http://1.usa.gov/12zorad ("[T]he mere presence of a reverse payment in the Hatch-Waxman context is not sufficient to establish that the settlement is unlawful."). Petitioner has not offered any explanation for its change of heart, and its new approach is incorrect as a matter of economics and common sense.

B. The Proposed "Presumption Of Illegality" Would Constrain Settlement Options In A Wide Variety Of Circumstances

Every settlement of patent litigation involves consideration of some kind flowing to the alleged infringer; otherwise there would be no reason to settle. *See generally Asahi Glass Co. v. Pentech Pharm. Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J.), *appeal dismissed*, 104 Fed. Appx. 178 (7th Cir. 2004). With no bright lines, under Petitioner's proposed approach, every intellectual property owner that settles an infringement claim without authorizing immediate entry by the alleged infringer faces the prospect of lengthy and expensive antitrust litigation, for disputed issues of fact mean that neither dismissal on the pleadings nor dismissal at the summary judgment stage is likely to be available. But Petitioner's brief does not grapple with that issue.

Petitioner's effort to distinguish the "reverse payment" in this case from consideration that flows

in every other type of settlement is unavailing. In fact, there was no mere "direct payment of money" in this case; Solvay paid Watson for marketing AndroGel® to urologists, paid Paddock to act as a back-up manufacturer, and paid Par to market the drug to primary care physicians. Pet'r. Br. at 11. Petitioner alleges, however, that these agreements "made economic sense" only as payments for delayed generic entry because the services provided "had little value to Solvay." *Id.* at 12.

Even if these ancillary agreements, however, did involve "overpayments" (and how that might be determined is far from clear), the flow of consideration in these "reverse payments" cases is economically indistinguishable from the consideration that is commonly found in many litigation settlements. Endorsing Petitioner's proposed rule risks opening every patent settlement that does not result in immediate entry to antitrust challenge. Petitioner's proposed rule of law would mean that thousands of patent settlements outside the pharmaceutical context must be treated as "presumptively unlawful" and subject to "quick look" condemnation. The unprecedented overreach of Petitioner's proposed rule of law demonstrates its fundamental flaws.

The most common form of consideration in a patent settlement is a release of the patent owner's claim for damages. While, as we discuss above, a pharmaceutical patent holder will often have no damages claim against the alleged infringer because of the artificial act of infringement created by the Hatch-Waxman Act, that is not uniformly the case. Some generic drug makers launch "at risk" (after the expiration of the automatic 30-month stay), leading

to a damages claim for lost profits or a reasonable royalty. And, outside the pharmaceutical settlement context, it is common to settle infringement cases with an agreement by the infringer to withdraw its product from the market for some period of time while the patent holder compromises its damages claims by settling for less than the full damages it claims to be owed. If the patent holder has a risk adjusted expected damages recovery of $100 million and agrees to settle for $50 million, it has agreed to a "reverse payment" that is indistinguishable in effect from a $50 million cash payment. Either case involves a transfer of value worth $50 million from the patent holder to the alleged infringer.

In other cases the alleged infringer receives consideration that is less transparent, but consideration nonetheless. Imagine, for example, that the infringer expects to sell $200 million worth of infringing goods. If the patent owner agrees to a 25% royalty rather than a 50% royalty, it has transferred $50 million of value to the infringer. Would Petitioner second-guess every settlement with a running royalty to determine whether the royalty rate is a disguised reverse payment?

Petitioner suggests that this conundrum can be avoided if one looks only to consideration that the infringer would not receive even if it prevailed in the litigation, which Petitioner suggests "implies the other terms of the settlement are disconnected from any justification they might otherwise have had in the Patent Act." Pet'r. Br. at 30. But this is nothing more than *ipse dixit*; Petitioner does not explain *why* consideration only matters if the infringer would not receive it, even if it prevailed. Release of $50 million in damages claims or a $50 million reduction in

royalty payments is real consideration, even if the infringer would not have to pay either damages or royalties if it prevailed. Patent litigation is an uncertain business, and because we are speaking here only of non-sham litigation, alleged infringers are by definition facing exposure. Petitioner does not and cannot explain why a $50 million reduction in an accused infringer's exposure is less "presumptively unlawful" than, for example, the $2 million payment to Paddock to act as a backup manufacturer in this case.

Regardless, many settlements involve consideration to the alleged infringer that the infringer would not receive if it prevailed in the litigation—consideration that Petitioner acknowledges constitutes a "reverse payment" under its proposed test. For example, it is common for infringement litigation to settle with a broad release (including potential infringement claims under patents not asserted in the litigation). Some infringement litigation settles with the infringer receiving an exclusive or quasi-exclusive license in a field of use or territory. Other infringement litigation settles with a know-how license coupled with the patent license or with a license to patents not asserted in the lawsuit. All of these settlements give the alleged infringer something it would not get if it simply litigated through trial and appeal (a broad release, exclusive rights, or a know-how license or license to additional patents). But all would be "presumptively unlawful" under Petitioner's proposed rule.

C. There Is No Basis In This Court's Precedents To Apply The "Quick Look" Standard In This Case

This Court has held that conduct may be condemned using a "quick look" when "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets." *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 770 (1999). In *California Dental*, the Court held that "quick look" treatment was inappropriate because the challenged restrictions "might plausibly be thought to have a net procompetitive effect, or possibly no effect at all on competition." *Id.* at 771.

There is no basis to believe that "reverse payment" settlements, however defined, inevitably have an anticompetitive effect. Patent holders often prevail in infringement litigation, and any settlement that allows early entry by an infringer that would otherwise be off the market for the life of the patent has a net procompetitive effect regardless of the presence of a reverse payment.[12]

This is not a hypothetical argument. The cases reveal concrete examples of pharmaceutical patent owners that settled with some generics with a reverse payment and early entry and then litigated with other generics and prevailed, keeping these later infringers off the market. For example, after the settlement at issue in the Second Circuit's *Cipro* case, the patent was repeatedly upheld as valid in other Hatch-Waxman litigation, meaning that absent

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[12] It goes without saying that a "rudimentary understanding of economics" is of no assistance in determining the strength of a patent or the likely outcome of infringement litigation.

the settlement there likely would have been no early entry by any generic at all. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 519-520 (E.D.N.Y. 2005) (summarizing results of litigation where Bayer defeated two generic companies' validity challenges on summary judgment and overcame another generic's validity challenge after a nine-day bench trial).

The same outcome occurred after the settlements at issue in *In re Tamoxifen Citrate Antitrust Litigation* were reached, 466 F.3d 187 (2d Cir. 2006), where the patent was repeatedly upheld as valid. *See Zeneca Ltd. v. Novopharm Ltd.*, No. 9601364, 1997 WL 168318 (Fed. Cir. Apr. 10, 1997); *Zeneca Ltd. v. Pharmachemie B.V.*, No. CIV.A.96-12413-RCL, 2000 WL 34335805 (D. Mass. Sept. 11, 2000).

Similarly, after Petitioner blocked a "reverse payment" settlement between Bristol-Myers Squibb and Apotex involving the drug, Plavix, BMS took the patent case to trial and won. *Sanofi-Synthelabo v. Apotex, Inc.*, 492 F. Supp. 2d 353, 397 (S.D.N.Y. 2007). These examples demonstrate that reverse payment settlements can have procompetitive effects by permitting entry that would not have occurred in the absence of the settlement.

Under *California Dental*, an agreement cannot be analyzed under the "quick look" approach unless someone with a "rudimentary understanding of economics" would conclude that the agreement is inevitably anticompetitive. Presumably the United States would concede that the Antitrust Division of the Department of Justice and the Office of the Solicitor General possess such a "rudimentary understanding of economics." The United States, over the signatures of both of those agencies, has

three times told this Court that "reverse payment" agreements are *not* inevitably anticompetitive and may in fact have *procompetitive* effects. The United States was obviously right in those three briefs; anyone possessing such a "rudimentary understanding" would instantly recognize that the settlements in *Cipro* and *Tamoxifen* did *not* have anticompetitive effects and that, as the United States previously told this Court, "[r]everse payments may have the salutary effect of facilitating efficient settlements that advance consumer welfare." Brief for the United States as *Amicus Curiae* at 9, *Andrx Pharms. v. Kroger, Co.*, 543 U.S. 939 (2004) N(o. 03-779), *available at* http://1.usa.gov/Xf3qhd.

Petitioner calls its version of the "quick look" doctrine the "inherently suspect" test. *See generally In re Polygram Holding, Inc.*, 136 F.T.C. 310 (2003), *aff'd sub nom. Polygram Holding v. FTC*, 416 F.3d 29, 35-36 (D.C. Cir. 2005). According to Petitioner, the inherently suspect test is reserved for conduct that "past judicial experience and current economic learning have shown to warrant summary condemnation." *Id.* at 344-45. Here, of course, with the exception of the Third Circuit's aberrant decision in *K-Dur*, "judicial experience" with "reverse payments"—six appellate decisions from three circuit courts—shows that summary condemnation is *not* warranted.

Indeed, Petitioner is itself a relatively recent convert to the application of the "inherently suspect" or "quick look" doctrine to these cases. In its 2003 decision challenging Schering's "reverse payment" settlements, Petitioner concluded that "[i]n cases like this one, where the conduct is not inherently suspect,

the prosecutor has the burden of demonstrating actual or likely market effects by reference to facts specific to the case." *In re Schering-Plough Corp.*, 136 F.T.C. 956, 969 (2003), *vacated by Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

There have been no significant developments in economic or judicial thinking since the United States filed its briefs in *Joblove*, *Andrx* and *Schering*, or since Petitioner's own decision in *Schering*. This Court's "quick look" precedents and Petitioner's analogous "inherently suspect" precedents make plain that patent settlements cannot be condemned with a "quick look."

CONCLUSION

As explained in detail in Respondents' brief, the so-called "scope of the patent test" adopted by the Eleventh, Second and Federal Circuit Courts of Appeal in evaluating Hatch-Waxman settlements is firmly grounded in well-established precedents.

The Court should affirm the judgment of the Court of Appeals for the Eleventh Circuit and hold that reverse payment settlements should be reviewed under the scope of the patent test.

Respectfully submitted,

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APPENDIX

APPENDIX

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AMICUS CURIAE BRIEF

RECORD
AND
BRIEFS

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FEDERAL TRADE COMMISSION,

Petitioner,

v.

WATSON PHARMACEUTICALS, INC., ET. AL.,

Respondents,

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF OF *AMICUS CURIAE* KNOWLEDGE ECOLOGY INTERNATIONAL IN SUPPORT OF PETITIONER

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INTEREST OF AMICUS CURIAE[1]

Knowledge Ecology International ("KEI") is an international non-profit, non-governmental organization that searches for better outcomes, including new solutions, to the management of knowledge resources. In particular, KEI is focused on the management of these resources in the context of social justice. KEI is drawn to areas where current business models and practices by businesses, governments or other actors fail to adequately address social needs or where there are opportunities for substantial improvements. Among other areas, KEI has expertise in access to medical technologies and access to knowledge issues. KEI has extensive experience in analyzing the costs of drug development and the role of generic competition in driving down prices so that consumers can purchase affordable medicines.

KEI is concerned about the impacts the Eleventh Circuit opinion immunizing reverse payment settlement agreements, also known as "pay-for-delay," from antitrust scrutiny will have on the availability of affordable generic medicines. If allowed to stand, the opinion below is likely to permit pharmaceutical companies to preserve improper monopolies over weak patents and greatly delay the entry of generics into the market, thereby adversely impacting patients.

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[1] Counsel for petitioner has filed consent to the filing of all *amici curiae* briefs. Consent from each of the Respondents' counsel have been filed with the Clerk of Court. No counsel representing any party to the case authored this brief, in whole or in part, and no counsel or party made any monetary contribution to the preparation or submission of the brief.

SUMMARY OF THE ARGUMENT

The present case involves pay-for-delay settlement agreements, also known as reverse payment agreements, where a branded pharmaceutical company pays a generic firm in order to delay the entry of the generic company into the market. Branded pharmaceutical companies have a clear incentive to preserve their monopolies, particularly over weak patents that are likely to be found invalid if patent litigation continues on the merits, and therefore enter into the pay-for-delay agreements where they offer generic challengers an opportunity to directly share in the monopoly profits of the sales of a drug. The Eleventh Circuit improperly applied the "scope-of-the-patent" test to pay-for-delay agreements finding such settlements valid because their exclusionary effect falls within the exclusive right of a patent, effectively immunizing pay-for-delay from antitrust scrutiny and ignoring the merits of the actual patent-at-issue. By contrast, the Third Circuit applied a more flexible rule that preserves important incentives to challenge weak patents by holding that pay-for-delay agreements are presumptively anticompetitive.

Proponents of heightened protection of patented products such as pharmaceuticals often fail to acknowledge the many other rewards those investing into research and development receive. A wide range of incentive mechanisms exist to induce investment in pharmaceutical drug development and such investors are well-compensated through non-patent mechanisms. Such rewards include, among

others, exclusive rights over clinical test data used to register drugs, tax credits, or vouchers for accelerated consideration of new drug approvals. The federal government also provides funding through grants and contracts to support research and development of pharmaceutical products.

In addition to receiving compensation outside of the patent system, the costs of developing new drugs are often not as high as claimed by the pharmaceutical industry. Proponents of heightened patent protection cite high costs of research and development, but the figures relied on by the pharmaceutical industry are often inflated and rely on faulty studies.

Pay-for-delay settlement agreements impede one of the intended purposes of the Hatch-Waxman Act to encourage generic firms to challenge weak patents and should be considered presumptively anticompetitive. A compelling public policy exists to promote the challenging of weak patents so that generic entry into the market occurs at an earlier date and consumers can purchase pharmaceutical drugs at a more affordable price. Immunizing pay-for-delay settlements from antitrust scrutiny, as the Eleventh Circuit opinion does, removes these incentives and harms the public interest by permitting branded pharmaceutical companies to buy off generic competitors. This Court should instead adopt the more flexible and pro-competitive, pro-consumer approach adopted by the Third Circuit.

ARGUMENT

I. JUSTIFICATIONS FOR HEIGHTENED PATENT PROTECTION AND IMMUNIZATION FROM ANTITRUST SCRUTINY FAIL TO TAKE INTO ACCOUNT OTHER REWARDS AVAILABLE TO THE PATENT HOLDER

Among the common justifications for strong protection of patents in the area of pharmaceuticals are those that point to high costs of research and development and the assertion, without evidence, that patents are necessary to protect and reward investments in the development of new products. Indeed, the Eleventh Circuit, in the opening paragraph of its opinion in the present case, pointed to the high costs of drug development. As will be discussed further in Part II.C, *infra*, the putative high costs cited by the Eleventh Circuit and other proponents for high protection of patented products are supported by industry consultant studies that rely upon facts highly distinguishable from the present case and cannot be considered relevant to or supportive of its conclusions.

These justifications also fail to take into account the numerous non-patent mechanisms that exist in the United States to reward research and development in the pharmaceutical industry.[2]

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[2] Amicus curiae does not necessarily endorse the use of each of the alternative mechanisms discussed herein, particularly the manner in which some have been implemented. This discussion of reward mechanisms serves as examples of the wide range of incentives that are currently used in the United

Patents as incentives have known deficiencies and are not the sole reward mechanism to stimulate investments in research and development for new drugs.

One common *sui generis* protection that is used in parallel to the patent system is the application of a limited time exclusive right to rely on clinical test data used to register new drugs or vaccines. Food, Drug and Cosmetics Act, New Drugs, 21 U.S.C. §355. These exclusive rights over test data include five years of protection for new chemical entity pharmaceutical products, an additional three years of protection where the pharmaceutical applies to treat a new indication, and twelve years of protection for new biologic drugs. *Id.* During this period, the originator of the test data can exclude others from relying on the data even if the patent on the pharmaceutical product has already expired. While exclusive rights over test data have their own shortcomings, it represents one way in which the originator of the test data, usually the holder of the patent, receives compensation outside the patent system.

Another existing non-patent incentive provided in the area of pharmaceutical drugs is the receipt of a fifty-percent tax credit for companies investing in the clinical trials for development of new "orphan" drug indications, that is a drug used to treat a rare medical condition. Internal Revenue Code, Clinical testing expenses for certain drugs for rare diseases or conditions, 26 U.S.C. §45C. Notably,

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States to reward research and development in the pharmaceutical industry.

in the present case, on February 5, 1996, the product-at-issue, AndroGel, received an orphan drug designation for the treatment of weight loss in AIDS patients.

Pharmaceutical companies can also benefit from a pediatric exclusivity extension. Food and Drug Administration Modernization Act of 1997, Federal Food, Drug and Cosmetic Act, 21 U.S.C. §355(a). The pediatric extension permits certain new drug applications to obtain an additional six months of marketing exclusivity where the applicant submits information to the FDA relating to the use of the product to treat a condition afflicting the pediatric population. *Id.* The pediatric extension is an add on period of exclusive to existing marketing exclusivity or patent protection. Indeed, in the present case, AndroGel has received such a six month extension of its marketing exclusivity under this law.

Congress has also created a "Priority Review Voucher" designed to stimulate research and development in treatments for rare tropical diseases. This transferable voucher permits accelerated consideration of new drug approvals as a reward for a company that registers a drug for a category of rare disease, such as cholera or leprosy. Food, Drug and Cosmetic Act, Priority Review to Encourage Treatments for Tropical Diseases, 21 U.S.C. §360n.

In addition to various incentive and reward programs, governments support medical research and development through a number of grant and contract programs. For example, among the trials included in the National Institutes of Health (NIH) ClinicalTrials.Gov database, the U.S. government

has funded 169 clinical studies involving testosterone beginning in 1985, including eleven studies that began before the Federal Drug Administration (FDA) approval of AndroGel. Simialrly, a search of the NIH RePorter database using the search term testosterone identifies 7,655 NIH-funded projects. These grants and contracts are associated with 230 clinical studies. There were 1,964 NIH funded projects in the periods including and between fiscal years 1989 to 1999, and more than $1.2 billion in project funding from fiscal year 2000 to the present. In 2012 alone, 3,944 scientific articles were published citing funding from these grants. The volume of clinical studies and projects funded by the NIH on testosterone alone demonstrates that the costs of pharmaceutical drug development are supported by the federal government and do not fall solely on branded pharmaceutical companies.

The above incentive mechanisms and rewards, in addition to the federal funding of medical research, highlight the fact that patent holders often receive numerous benefits that fall outside the patent system and are greatly supported by federal grants. These mechanisms and federal funding all serve to support and induce investments into the research and development of pharmaceutical products apart from the reward of a patent. The Eleventh Circuit opinion fails to take into account the wide range of ways pharmaceutical companies are compensated or rewarded outside of the patent system.

II. JUSTIFICATIONS FOR HIGH PATENT PROTECTION DUE TO COST OF PHARMACEUTICAL DRUG DEVELOPMENT OFTEN RELY ON INFLATED DATA AND DO NOT PROVIDE A PERSUASIVE REASON TO IMMUNIZE PAY-FOR-DELAY FROM ANTITRUST SCRUTINY

Proponents of the scope-of-the-patent test justify pay-for-delay, in part, because of the putative high costs of research and development. The Eleventh Circuit in its opening paragraph of the opinion below justified its decision in part on the high costs of developing new drugs and cited a 2010 article by Dickey, Orszag, and Tyson as support. *FTC v. Watson Pharmaceuticals, Inc.*, 677 F.3d 1298, 1300 & n.1 (11th Cir. 2012) (*citing* Bret Dickey, Jonathan Orszag & Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 ANNALS HEALTH L. 367, 369 & n.10 (2010)).

The Dickey, Orszag and Tyson article, which "was supported by funding from the Pharmaceutical Research and Manufacturers of America (PhRMA)" essentially reports on research regarding drug development costs that have been published by pharmaceutical industry consultants and industry funded institutions. The pharmaceutical industry funded authors cite a two page backgrounder by the Tufts Center for the Study of Drug Development. also supported by the pharmaceutical industry, which it turn reports, without evidence, an industry claim that "only 1 of every 5,000 medicines tested is eventually approved." Dickey, Orszag and Tyson at

n. 8. While it is undoubtedly true that academic researchers and companies involved in drug development research screen many different compounds for each approved drugs, the 1 in 5,000 number gives the illusion these risks have actually been quantified by experts when, in fact they have not. Even as a stylized fact, the 1 in 5,000 figure does not provide context regarding the expense of screening substances at early stages of development, which can include a variety of highly mechanized screening processes and computer simulations.

Dickey, Orszag and Tyson also cite three papers co-authored by Tufts researcher and pharmaceutical company consultant Joseph DiMasi, that make a number of assertions about the costs of drug development and the number of new drugs that recoup R&D investments. In particular, they present DiMasi's arguments that, "Recent studies estimate that the average new drug took 10 to 15 years and cost over $1.3 billion (including both direct costs and opportunity costs) to develop and . . only 20 to 30 percent of those approved eventually recoup their R&D." Dickey, Orszag and Tyson at n.11 (citing Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 MANAGERIAL AND DECISION ECONOMICS 469-79 (2007).

While it is true that the three DiMasi studies cited by Dickey, Orszag and Tyson do make these claims, several reasons exist to call into question the specific claims and the relevance in the context of this case. Certainly the Eleventh Circuit should have avoided citing the $1.3 drug development estimate to reach the conclusion that "no rational

actor would take that kind of risk . . . without the prospect of a big reward," which is reduced where generics are able to compete in the market.

The true costs of drug development have been largely secretive. In examining various estimates of drug development costs, Morgan, Grootendorst, Lexchin, Cunningham and Greyson note:

> Despite three decades of research in this area, no published estimate of the cost of developing a new drug can be considered a gold standard. Existing studies vary in their methods, data sources, samples, and therefore estimates. While some methods are methodologically strong and some findings have been widely cited, the fact that the data and even the subjects of investigation are kept secret make it impossible to assess validity and reliability. Steve Morgan, Paul Grootendorst, Joel Lexchin, Colleen Cunningham, and Devon Greyson, *The Cost of Drug Development: A systematic review*, 100 HEALTH POL'Y 1 (2011).

The continued secrecy of the data of various industry estimates of drug development costs make it challenging to evaluate such estimates, particularly when there is so much variance in drug development costs and the samples in the DiMasi and other studies are acknowledged to be selective. Even if the estimates were reasonable, within the bounds and

context for the products being considered, they do not make sense in the present case.

In a 2012 Astrazeneca funded study of drug development costs, Mestre-Ferrandiz, Sussex and Towse note that "mean estimates of R&D costs per successful drug should be treated with caution. While useful to provide an overall picture, cost differences around the mean are important." Jorge Mestre-Ferrandiz, Jon Sussex & Adrian Towse, *The R&D Cost of A New Medicine* at 72 (2012), available at http://www.ohe.org/publications/article/the-rd-cost-of-a-new-medicine-124.cfm. Furthermore, the authors suggest that caution should be taken "because of important differences in the studies. particularly in the use of different databases of drugs. Moreover, important differences exist across subgroups of drugs—for instance, by therapeutic area, by firm size and by compound origin."

Here, it is useful to return to another DiMasi assertion including in the article by Dickey, Orszag and Tyson. Based upon the vast differences in development costs from one compound to another, as illustrated vividly by the facts in the AndroGel case, one cannot conclude that only twenty to thirty percent of those drugs approved eventually recoup their research and development investment. Dickey, Orszag and Tyson at 7. Instead, it is more likely that the highly variable research and development outlays for products provides opportunities for companies to register products with smaller market sales potential, because the drug development costs for that particular compound are lower, due to the feasibility of registering a drug with smaller trials, or benefitting from lower per-patient

outlays on trials, shorter development time, or registering products that have benefited from various federal subsidies and specialized tax credits.

In the present case, it is notable that the drug AndroGel was a new formulation of an older drug than had been used to treat patients for more than fifty years. The product was not self originated, but instead "licensed-in" from another company. The product began clinical testing in 1996, and was approved for marketing by the FDA on February 28, 2000. AndroGel received an 1996 Orphan drug designation for the treatment of AIDS related wasting. And as noted above, testosterone was the subject of thousands of grants and 169 federal government funded clinical trials, including 11 clinical studies that were started before AndroGel was approved for marketing in 2000.

The FDA approval of AndroGel was based upon a single Phase III trial (UMD-96-017) which involved just 227 patients, and all of the company's trials, including an observational trial of 106 patients, totaled 471 patients in all.[3]

---

[3] The clinical trials of AndroGel consisted of seven trials with a total of 471 patients:

Trial	Patients	Phase
UMD-96-017	227	Phase III
UMD 96-012	10	Phase I
UMD 98-035	106	Observational
UMD 98-037	45	
UMD 98-038	35	
UMD-98-039	30	
UMD-98-044	18	Phase II
Total	471	

These above facts must be taken into account in estimating the costs of drug developments, but the DiMasi papers in 2003 and 2007 do not do so. While AndroGel's approval was based upon trials involving 471 patients, DiMasi reported a mean of 5,303 patients in clinical studies. *See* DiMasi at n. 41. The DiMasi figure therefore uses a figure several orders of a magnitude larger than the actual number of patients in the present case.

Furthermore, while the time between initial clinical testing of AndroGel and FDA approval took less than four years, the time from initial testing to marketing approval in the DiMasi's sample took 90.3 months on average, or 7.525 years. The shorter period of testing for AndroGel means the cost of capital adjusted figures would be much lower.

Additionally, DiMasi's study excluded licensed-in products and included only self generated products. AndroGel, by contrast, was a licensed in product. Elsewhere DiMasi has estimated that the overall clinical approval success rate for licensed-in products is much higher than for self-originated drugs (27% compared to 16%). Mestre-Ferrandiz at 53. The difference in overall success rates lowers the costs, when compared to the products in the DiMasi study.

Another important consideration is that in DiMasi's 2003 study, he dismissed the importance of orphan products and government funded research. As noted in the preceding section, *supra*, AndroGel received an Orphan Designation in 1996, and the

active ingredient in AndroGel was the subject of thousands of NIH funded studies.

The Eleventh Circuit relied upon inflated estimates of the average cost of drug development put forth by consultants that are advocates for the pharmaceutical industry. Further, this average was based upon secret data sets which were described by the industry consultants as having completely different characteristics than the characteristics of the research and development associated with AndroGel. These differences suggest that AndroGel was in fact a far less expensive product to bring to market.

Furthermore, regardless of the costs of drug development, it is important to keep in mind the Constitutional rationale for the patent system, to "promote the Progress of Science and useful Arts," U.S. CONST., Art. 1, §8, cl. 8. The patents-at-issue in most pay-for-delay cases are weak ones that do not meet the statutory standards for patent protection, often failing the "non-obvious" or "novelty" requirements. Immunizing pay-for-delay from antitrust scrutiny gives parties an incentive to settle rather than litigate the patents and permits branded pharmaceutical companies to protect unwarranted monopolies over products that do not promote the progress of science and do not represent true innovation. Additionally, even absent any patent protection, the costs of development for AndroGel would have been fully recouped by the company given the period of exclusive rights over clinical test data it was granted and discussed in Part II, *supra*, and the low outlays required for the small clinical trials used to register the product.

Pharmaceutical companies should be spending research and development dollars on treatments that represent true innovation that improve the therapeutic benefit or treat new conditions rather than merely creating new forms of old drugs. Permitting pay-for-delay reduces incentives to invest in truly new, innovative products and instead encourages reliance on preserving or creating new monopolies for old products.

III. PAY-FOR DELAY SETTLEMENT AGREEMENTS IMPEDE THE INTENDED PURPOSE OF THE HATCH-WAXMAN ACT PROVISIONS DESIGNED TO PROVIDE INCENTIVES TO PROMOTE GENERIC ENTRY INTO THE MARKET

A. The Hatch-Waxman Act Included Incentives for Generic Pharmaceutical Companies to Challenge Weak Pharmaceutical Patents Thereby Promoting Generic Competition

In 1984, Congress passed what became known as the Hatch-Waxman Act. 21 U.S.C. §355. A portion of the Hatch-Waxman Act served to provide an incentive to generic manufacturers to challenge weak patents in order to hasten generic pharmaceutical entry into the market and promote generic competition. Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, H.R. REP NO. 98–857, at 4 (1984), H.R. REP. NO. 98–857, at 4 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2688. The Hatch-Waxman act created the abbreviated new drug application, known

as "ANDA," to allow generic manufacturers to rely on the previously approved NDA information, that is the clinical trial data, by demonstrating bioequivalence. 21 U.S.C. §355(j). A generic firm can file what is known as a "Paragraph IV" certification that its drug does not infringe on the existing patents, or that such patents are invalid. 21 U.S.C. §355(j)(2)(A). The first generic manufacturer to file its application can obtain an 180-day exclusivity period where it essentially enters into a duopoly with the brand name manufacturer and no other generic competitors can enter the market during this 180-day period. 21 U.S.C. §355(j)(5)(B)(iv). As confirmed by federal courts, only the first generic company to apply, not the first to successfully defend its case, is eligible for the 180-day exclusivity period. *Mova Pharm. Corp. v. Shalala*, 955 F.Supp. 138 (D.D.C. 1997), *aff'd by*, 1040 F.3d 1060, 1074 (D.C. Cir. 1998).

Once a generic company has filed an ANDA with a "Paragraph IV" certification, the brand name pharmaceutical company can file a patent infringement claim against the generic company. Instead of litigating the case on the merits, though, the branded pharmaceutical firm and the generic company may choose to settle. These settlements often result in pay-for-delay agreements, also known as reverse payment settlements, where the branded firm will pay the generic firm and, as part of the agreement, the generic firm will agree to delay entry into the market until a specified date.

Rather than continue with litigation, the generic firm may instead accept the payment offered by the pharmaceutical company. In essence, many of

these agreements result in branded manufacturers to pay to exclude generic competition from the market by offering competitors a share of the monopoly profits. The weaker the patent held by the branded company, the greater its incentive to offer a reverse payment to the generic firm.

Significantly, branded pharmaceutical companies have a clear incentive to settle in many cases. Generic companies that have used the "Paragraph IV" certification target weak patents and these challenges have been largely successful when the cases are fully litigated on the merits. A study conducted by the FTC found that in seventh-three percent of patent litigation that was ultimately resolved by a court decision, the generic challenger prevailed. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration* (July 2002), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf

Although the settlement agreements generally claim that the branded company is paying for services of the generic company, such as for marketing work or backup production capacity, evidence suggests that the agreements are solely to preserve the monopoly. A 2009 survey found that outside of pay-for-delay settlement agreements, branded pharmaceuticals rarely contract generic firms for assistance in such activities and there are "no significant examples" of such work. C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 666-68 (2009). That branded pharmaceuticals rarely engage in such contracts with generic companies is unsurprising because generic firms "do not have substantial

promotion teams, for they seldom have major branded drugs to promote." *Id.*

By paying off the first generic filer, the branded firm removes the most motivated challenger and is therefore more likely to preserve its monopoly. The first generic filer has the greatest incentive to challenge the validity of the patent because of the 180-day marketing exclusivity period it receives if successful. Even with the amendments to the Hatch-Waxman Act that provide for forfeiture of the 180-day exclusivity period where there is "failure to market," it is possible that forfeiture does not apply to settlement cases. Hemphill at 660 (*citing* Letter from Gary J. Buehler, Dir., Office of Generic Drugs, FDA to Marc A. Goshko, Executive Dir., Teva N. Am. 5 N. 6 (Jan 17, 2008), available at http://www.fda.gov/ohrms/DOCKETS/dockets/07n0389/07n-0389-let0003.pdf which notes that without a court entering a final judgment of invalidity or non-infringement, subsequent generic applicants cannot initiate forfeiture proceedings) (*but* noting other possible interpretations). Thus, a subsequent generic filer that challenges the validity of the branded patent may find upon conclusion of patent infringement litigation that he cannot benefit from the 180-day marketing exclusivity; the day the subsequent generic filer is able to enter the market, so too other generic firms may also market their products. As a result, the branded firm has a large incentive to settle with the first generic filer.

The outcome of the case will have an enormous impact on the availability of affordable generic medicines and, therefore, the cost of treatment. A 2009 survey demonstrated that pay-

for-delay settlements are on the rise. C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 657 (2009). This survey tracks the rise, fall, and rise again of such settlement agreements noting that when the FTC initiated antitrust actions, the reverse-payment agreements diminished. *Id.* After the FTC lost these suits, however, firms began to enter into pay-for-delay settlements again and such agreements appear to be on the rise once again. *Id.* This Court's ruling will therefore likely have a significant impact on whether challenges to the patents of pharmaceutical products reach the actual merits and, subsequently, whether affordable generic medicines reach patients and consumers at an earlier date.

Congress passed the "Paragraph IV" portion of the Hatch-Waxman Act in order to promote challenges to invalid drug patents and promote earlier generic entry into the market. Where the incentives to such challenges are minimized or eliminated, such as is the case for pay-for-delay settlement agreements, the public interest in attaining lower cost drugs through the availability of generic competition is disserved. Pay-for-delay settlements are likely to result in a frustration of one of the key objectives of the Hatch-Waxman Act. Rather than promoting challenges to weak patents, pay-for-delay agreements instead promote settlement agreements that preserve monopoly power and keep prices high for consumers.

B. The Eleventh Circuit Decision Immunizes Pay-For-Delay Agreements from Antitrust Scrutiny and Reduces the Likelihood of Faster Entry of Generic Medicines Into the Market, Impeding a Key Objective of the Hatch-Waxman Act.

The rule adopted by the Eleventh Circuit in the present case immunizes pay-for-delay settlement agreements from antitrust scrutiny as long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent. *FTC v. Watson Pharmaceuticals, Inc.*, 677 F.3d 1298 (11th Cir. 2012). In this *per se* rule of legality, the only exception applies where sham litigation or fraud occurred. *Id.* at 1312. This rule, also known as the "scope-of-the-patent" test, effectively exempts reverse payment agreements from antitrust scrutiny despite the fact that in other contexts, reverse payments have often been found to be anti-competitive. *See, e.g., Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46 (1990) (per curiam) (holding that payment by one bar review provider to a competitor to withdraw from the market violated antitrust law).

The "scope-of-the-patent" test is based on the erroneous assumption that the patent is legitimate and would be upheld if litigation concluded on the merits. However, as noted in the previous section, the majority of Paragraph IV challengers that follow through to the final judgment win and the challenged patent is found to be invalid. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration* (July 2002), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf

Where the patent is weak, the branded pharmaceutical company has an obvious incentive to settle the case and pay the generic firm some portion of its monopoly profits rather than having a court rule that its patent is invalid and invite generic competition.

In applying the "scope-of-the-patent" test, courts completely ignore the inquiry of whether the patent is valid or not. Certainly, if the patent is a valid one, the patent-holder can exercise its exclusionary rights. However, in ignoring the strength of the patent and assuming its validity, the "scope-of-the-patent" rule results in an absurdity. If a patent is actually invalid then it does not have any scope; permitting the reverse-payment settlement goes well beyond what would be the scope of an invalid patent.

As a result, a finding of *per se* lawfulness of pay-for-delay agreements permits the patent holder to continue to exercise its monopolies over potentially weak patents. By maintaining monopoly control, the prices remain higher for a longer period than warranted in many cases and consumers are harmed because they are forced to pay high, sometimes unaffordable prices. Kaiser Family Foundation, *Healthcare Costs: A Primer, Key Information on Healthcare Costs and Their Impact* 23 (2012) (reporting that twenty-five percent of families did not fill a medical prescription and seventeen percent cut pills or skipped doses due to the high costs).

The branded pharmaceutical company has an incentive to pay off the first generic challenger

because in doing so, the company removes the firm that would benefit from the 180-day exclusivity and, thus, the most motivated challenger. *See* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 NEW YORK UNIV. L. REV. 1553, 1585 (2006). Removing the most motivated challenger clearly impedes the Congressional intent of the provisions of the Hatch-Waxman Act that provide an incentive for generic firms to challenge weak patents.

C. The Third Circuit Rule that Pay-For-Delay is Presumptively Anticompetitive Strikes the Appropriate Balance Between Promoting Progress and Protecting the Public Interest

The Third Circuit, in contrast to the Eleventh Circuit, found that pay-for-delay settlement agreements are presumptively anticompetitive and unlawful in violation of antitrust laws and "contrary to the policies underlying the Hatch-Waxman Act and a long line of Supreme Court precedent on patent litigation and competition." *In re K-Dur*, 686 F.3d 197, 214 (3d Cir. 2012). The Third Circuit correctly noted that the "scope-of-the-patent" test assumes validity in the underlying patent. *Id.* In essence, pay-for-delay "permit[s] the sharing of monopoly rents between would-be competitors without any assurance that the underlying patent is valid." *Id.* at 216 (*citing U.S. v. Studiengeselschaft Kohle, m.b.H.*, 670 F.2d 1122, 1136 (D.C. Cir. 1981)).

Although public policy generally favors settlements over full litigation, it "should not

displace countervailing public policy objectives or, in this case, Congress's determination—which is evident from the structure of the Hatch-Waxman Act and statements in the legislative record—that litigated patent challenges are necessary to protect consumers from unjustified monopolies by name brand drug manufacturers." *In re K-Dur* at 217.

Furthermore, as this Court has noted, public policy also favors promotion of innovation and progress, including rejecting invalid patents in order to allow innovators to rely on the public domain. *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 101 (1993) (noting that while the purpose of the patent system is to promote the progress of science and innovation, the patent system also has an "important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain.").

Unlike the Eleventh Circuit which applied a hardfast rule that reverse payments fall within the scope-of-the-patent regardless of the actual strength of the patent, the Third Circuit rule is a more flexible one, creating a rebuttable presumption that such settlement agreements are anticompetitive. The parties to the pay-for-delay settlement may rebut the presumption that the reverse payment is unlawful by showing either that the agreed payment was for a purpose other than delaying entry or offers a pro-competitive benefit. *In re K-Dur* at 218. This pro-competitive rule promotes the goals and objectives of the Hatch-Waxman Act and protects the public interest by preserving the incentive to challenge weak patents, rather than providing an incentive to immunize weak patents from antitrust scrutiny by

allowing branded pharmaceutical companies to buy off its generic competitors. By making this rule a presumption only, the Third Circuit opinion leaves open the possibilities that a pro-competitive reason for the reverse-payment exists or that the payment was done for a reason other than delayed generic entry. Furthermore, the Third Circuit rule is more appropriate because it does not make false assumptions about the validity or invalidity of the underlying patents-at-issue in the litigation.

A rule that pay-for-delay agreements are presumptively anticompetitive preserves the Congressionally created incentives contained in the Hatch-Waxman Act to challenge weak patents and promote generic competition. If generic applicants cannot share in the monopoly profits of the branded pharmaceutical company, they are less likely to enter into settlement agreements and more likely to continue litigating against weak patents in order to earn the 180-day marketing exclusivity if the patent is found to be invalid. The Third Circuit approach is therefore not only more pro-consumer, but also supports the purpose of the Hatch-Waxman Act.

CONCLUSION

For the reasons discussed above, this Court should reverse the decision below, reject the "scope-of-the-patent" test and instead adopt a presumption that pay-for-delay settlement agreements are anti-competitive and violate antitrust laws.

Respectfully submitted,

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FEDERAL TRADE COMMISSION,
Petitioner,

v.

WATSON PHARMACEUTICALS, INC. et al.,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF OF LOUISIANA WHOLESALE DRUG COMPANY, INC., CVS PHARMACY, INC., RITE AID CORPORATION, WALGREEN CO., ECKERD CORPORATION, THE KROGER CO., SAFEWAY INC., ALBERTSON'S, INC., HY-VEE, INC., AND MAXI DRUG, INC. D/B/A BROOKS PHARMACY IN SUPPORT OF PETITIONER

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INTEREST OF *AMICI*[1]

Amici curiae are Louisiana Wholesale Drug Company, Inc., CVS Pharmacy, Inc., Rite Aid Corporation, Walgreen Co., Eckerd Corporation, The Kroger Co., Safeway Inc., Albertson's, Inc., Hy-Vee, Inc., and Maxi Drug, Inc. d/b/a Brooks Pharmacy. As direct purchasers and sellers of pharmaceutical products (or their assignees), *amici* have a strong interest in acquiring and distributing low-cost generic drugs. Because a generic drops to thirty percent or less of the price of the equivalent brand within a year of introduction, agreements by brand manufacturers to delay generic entry cost consumers – *amici*'s customers – billions of dollars each and every year. *See* FTC Staff Study, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 2 (Jan. 2010) ("FTC, *Pay-for-Delay*") (annual cost of $3.5 billion).

In recent years, *amici* have seen reverse payment agreements to settle Hatch-Waxman patent litigation proliferate. The previously accepted wisdom of pharmaceutical executives that such agreements are illegal and immoral has evaporated, encouraged by court opinions giving brand companies virtual carte blanche to pay competitors to delay competition. *See* FTC Bureau of Competition, *Overview of Agreements Filed in FY 2012*, at 2 (Jan. 17, 2013), available at http://www.ftc.gov/os/2013/01/130117mmareport.pdf

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[1] Pursuant to Supreme Court Rule 37.6, *amici curiae* affirm that no counsel for any party authored this brief in whole or in part and that no one other than *amici* or their counsel made a monetary contribution intended to fund the preparation or submission of this brief. The parties have consented in writing to the filing of this brief.

("FTC FY 2012 Overview") (reporting record number of potential pay-for-delay deals in 2012). Seeking to encourage competition in pharmaceutical sales, *amici* have participated as plaintiffs in nearly every private suit challenging the use of such reverse payments, including litigation concerning the agreements at issue in this case and *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012), *pets. for cert. pending* (Nos. 12-245, 12-265). Through that litigation, *amici* and their counsel have developed particular expertise concerning the lawfulness and anti-competitive effects of reverse payment agreements.

BACKGROUND

This case arises from petitioner FTC's complaint challenging reverse payment agreements between respondent Solvay (the manufacturer of AndroGel, a branded testosterone gel) and two would-be generic competitors, respondents Watson and Paddock (the latter partnering with respondent Par). Solvay sued the generic respondents for patent infringement pursuant to the Hatch-Waxman Act. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355). The generics countered that Solvay's patent was invalid and that their products did not infringe. The parties settled in 2006, with Solvay paying the generics millions of dollars to stay out of the market until 2015.

Because the district court granted respondents' motion to dismiss, this Court must decide the case based on the complaint's well-pleaded facts, construed in the light most favorable to petitioner FTC. But the Court should know that the facts of this case are representative of many other similar reverse

payment agreements. This brief brings to the Court's attention the extensive records compiled by *amici* in three similar cases plus a fourth in which a brand refused to make a reverse payment. The cases illustrate the severe threat to pharmaceutical competition posed by reverse payments.

I. K-Dur

K-Dur 20 ("K-Dur") was the subject of reverse payment agreements that gave rise to separate suits by the FTC and private plaintiffs. *See K-Dur*, 686 F.3d 197 (private suit); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (FTC action), *cert. denied*, 548 U.S. 919 (2006).

K-Dur is Schering's brand-name sustained release potassium chloride product. It treats potassium deficiencies, such as those that arise from the use of diuretics prescribed for high blood pressure. In 1997, Schering's annual U.S. sales of K-Dur were approximately $190 million. But Schering expected generic entry to reduce annual sales to $70 million or less by 2001. *K-Dur* 3d Cir. App. A-2026.

The potassium chloride compound in K-Dur was unpatentable. *K-Dur*, 686 F.3d at 203. However, Schering owned a formulation patent (the "'743 patent") claiming the controlled-release coating on the potassium chloride crystals. Particularly important, the '743 patent specifically claimed the use of ethylcellulose, a standard pharmaceutical ingredient, with a viscosity (resistance to flow) of greater than 40 centipoise (cp) (a measure of viscosity). Schering listed the patent in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book").

In November 1995, generic manufacturer Upsher filed the first Abbreviated New Drug Application ("ANDA") for generic K-Dur. Upsher's generic product used Ethocel 20, an ethylcellulose product with a viscosity of only 18-22 cp, significantly lower than the minimum 40 cp viscosity claimed by Schering's patent. Upsher provided a Paragraph IV certification that its product would not infringe the '743 patent. Schering responded by suing Upsher for infringement.

Upsher represented to the court that Schering's infringement claims were "baseless and could not have been made in good faith." *K-Dur*, 686 F.3d at 205; *K-Dur* 3d Cir. App. A-6972-73; A-6772. Schering had secured its patent only by surrendering the use of ethylcellulose with a viscosity of less than 40 cp. *K-Dur*, 686 F.3d at 205. Because Upsher intentionally designed its product to use subject matter that Schering had surrendered, the doctrine of prosecution history estoppel precluded any finding that Upsher's product infringed Schering's patent. *K-Dur* 3d Cir. App. A-6972-73; A-6772.

In settlement negotiations, Upsher repeatedly asked Schering to pay it to delay introducing generic K-Dur, but Schering repeatedly responded that such a payment would violate the antitrust laws. *K-Dur*, 686 F.3d at 205.

On June 17, 1997, the parties argued summary judgment motions. In that argument, the district judge repeatedly challenged Schering's allegation that Upsher's product using low-viscosity ethylcellulose infringed the '746 patent, which expressly claimed a viscosity of greater than 40 cp. *See, e.g.*, *K-Dur* 3d Cir. App. A-7110 ("You're saying 20 is 40?");

id. at A-7111 ("That's what you're saying 20 is 40?"); *id.* at A-7123 ("Don't words mean anything?").

Schering and Upsher settled just hours before the district court was to rule on the summary judgment motions. *K-Dur*, 686 F.2d at 205. Schering agreed to pay Upsher $60 million. In exchange, Upsher agreed to delay generic K-Dur for over four years. *Id.* The agreement also granted Schering licenses for several other Upsher products. After entering the reverse payment settlement, Schering predicted that its sales of K-Dur would grow rather than decrease as was expected had a generic been introduced. *K-Dur* 3d Cir. App. A-2026.

About a year after settling with Upsher, Schering made another reverse payment – this time to generic manufacturer ESI, which had filed a subsequent ANDA to sell generic K-Dur. ESI agreed not to market any generic version of K-Dur before January 2004, and Schering agreed to make a payment of up to $10 million contingent on the timing of FDA approval of ESI's generic. *K-Dur*, 686 F.3d at 206. The maximum payment corresponded to the earliest anticipated FDA approval date and decreased if delays in FDA approval rather than the parties' agreement prevented generic entry. *Id.*

In subsequent private antitrust litigation, *amici* presented a detailed economic expert report demonstrating that Schering's predicted losses from generic entry and Upsher's predicted gains would have allowed them to settle their patent dispute without a reverse payment. *K-Dur* 3d Cir. App. A-3158-64, A-3818. But a settlement without a cash payment would necessarily have had to grant Upsher a much earlier generic entry date, thereby benefitting consumers. *Id.* at A-3158-64. *Amici*'s expert also dem-

onstrated that Hatch-Waxman litigation can almost always be settled without a reverse payment. *See* Christopher Leffler & Keith Leffler, *Settling the Controversy Over Patent Settlements: Payments By the Patent Holder Should Be Per Se Illegal*, 21 RESEARCH IN LAW & ECON. 477, 483-84 (2004) ("Leffler & Leffler, *Settling the Controversy*").

II. Cipro

Cipro is a branded antibiotic sold by Bayer. Prior to generic entry, it had sales of over a billion dollars. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 538 n.22 (E.D.N.Y. 2005). Bayer estimated that it would lose between $510 million and $826 million in Cipro sales in the first two years of generic competition. *Id.* at 522.

Generic manufacturer Barr filed the first ANDA to sell generic Cipro. Because Bayer's patent claimed the active compound (ciprofloxacin) in Cipro, Barr's generic necessarily infringed, but Barr maintained that the patent was invalid. *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 102 n.5, 106 (2d Cir. 2010), *cert. denied*, 131 S. Ct. 1606 (2011). Barr entered into an agreement with Rugby (then a subsidiary of HMR) to share the costs of any patent litigation and any revenues arising from it. *Arkansas* 2d Cir. App. A-476.

After Bayer sued Barr for patent infringement, the parties settled on the eve of trial. Bayer acknowledged that Barr had raised a "substantial question" as to the patent's validity. *Arkansas* 2d Cir. App. A-996.

Bayer paid Barr $49.1 million and agreed to either supply ciprofloxacin to Barr to sell under license (for a royalty to Bayer of 70% of Cipro's average sell-

ing price) or to make quarterly payments beginning January 1998. *Arkansas Carpenters*, 604 F.3d at 102 & n.8. To avoid licensed generic competition, Bayer ultimately paid Barr an additional $349 million to stay out of the market. *Id.*

The payments gave Barr and its partner between 97% and 200% of the profits that they would have earned had they won the patent litigation and entered the market. *Arkansas* 2d Cir. App. A-5835; A-3427-28. Under the optional license, Barr would have entered the market at a substantial discount to branded Cipro, generating at least $125 million to $200 million in consumer savings. *Id.* at A-5931; A-5842. Bayer's reverse payments purchased relief from these consumer savings.

The agreement prohibited Barr and HMR/Rugby from supporting any other generic challenge to the '444 patent and disabled Barr's outside counsel from representing other generic manufacturers by requiring that they switch sides and represent Bayer. *Arkansas Carpenters*, 604 F.3d at 106; *Arkansas* 2d Cir. App. A-2796-97; A-2825.

The agreement eliminated generic competition for at least three years. *Id.* at A-5827. A second challenger could not have entered any earlier because it would have had to prepare and file a Paragraph IV ANDA and then wait out the automatic 30-month Hatch-Waxman stay. 21 U.S.C. § 355(j)(5)(B)(iii).

By the time another generic was in a position to enter the market, Bayer's patent was already near expiration, leaving that generic insufficient time to litigate its best challenge to the patent – that Bayer had secured the patent through inequitable conduct. *Arkansas* 2d Cir. App. A-4901-02; A-8356.11. Bayer

prevailed on the remaining, weaker defenses. *Arkansas Carpenters*, 604 F.2d at 102 n.9.

III. Provigil

The drug Provigil is used to treat sleep disorders. Its active ingredient, modafinil, is not patentable. However, brand manufacturer Cephalon owned a narrow patent claiming a particular formulation in which 95% of the modafinil particles had a diameter below 200 microns. *See King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 702 F. Supp. 2d 514, 521 (E.D. Pa. 2010). From 2004 to 2008, Cephalon's annual U.S. Provigil sales rose from $420 million to $920 million.

Four generic manufacturers – Teva, Ranbaxy, Barr, and Mylan – each submitted separate ANDAs on the same day containing Paragraph IV certifications that Cephalon's patent was invalid or not infringed. Cephalon sued all four generics.

Between December 2005 and February 2006, Cephalon entered into reverse payment agreements, under which each generic agreed to delay marketing generic Provigil for six years. *King*, 702 F. Supp. 2d at 521-23. Cephalon expected to pay up to $136 million to Teva, Ranbaxy, and Barr, and a further $45 million to Mylan. *Id.* at 522. As Cephalon's CEO candidly admitted: "We were able to get six more years of patent protection [from the settlement]. *That's $4 billion in sales that no one expected.*" John George, *Hurdles Ahead for Cephalon*, PHILA. BUS. J. (Mar. 20, 2006) (emphasis added).

Cephalon used this period of purchased exclusivity to encourage buyers to switch to Nuvigil, its patented successor brand product containing a closely related active ingredient. As Cephalon's Vice Presi-

dent of Investor Relations explained: "You should expect that we will likely raise Provigil prices to try to create an incentive for the reimbursers to preferentially move to Nuvigil." Jonathan D. Rockoff, *How a Drug Maker Tries to Outwit Generics*, WALL ST. J., Nov. 18, 2008, at B1.

A subsequently filed case involving a fifth generic competitor that was not paid off took years to litigate and is currently on appeal. In that suit, Cephalon's patent was invalidated on numerous grounds. *Apotex Inc. v. Cephalon, Inc.*, No. 2:06-cv-2768, 2011 WL 6090696, at *1 (E.D. Pa. Nov. 07, 2011) (holding that patent was unenforceable due to inequitable conduct and also was invalid because (1) the invention was on sale more than one year before the patent application was filed; (2) the invention was made by a French company not named in the patent application; (3) the subject matter was obvious; and (4) the written description was inadequate). Even had it been valid and enforceable, the patent was exceedingly narrow and was not infringed by Apotex's product that used larger modafinil particles than it specified. *See Apotex, Inc. v. Cephalon, Inc.*, No. 2:06-CV-2768, 2012 WL 1080148 at *1 (E.D. Pa. Mar. 28, 2012); *Apotex, Inc. v. Cephalon, Inc.*, No. 2:06-CV-2768, 2010 WL 3933274, at *6-8 (E.D. Pa. Oct. 7, 2010).

IV. Prozac

In 2001, Prozac, Eli Lilly's blockbuster antidepressant, had roughly $2.4 billion in annual sales. *See* Bethany McLean, *A Bitter Pill*, FORTUNE, Aug. 13, 2001, at 1. At that time, Lilly's patent on Prozac's active ingredient (fluoxetine) had expired. Generic manufacturer Barr asserted that Lilly's follow-on pa-

tent – which claimed the way that fluoxetine worked – was invalid for double patenting. *Id.* at 5.

Lilly sued Barr for patent infringement. Barr (which previously convinced Bayer to pay it $398 million to delay generic Cipro) demanded a reverse payment of at least $200 million to settle the case. But Lilly refused. At that time – before the Second, Eleventh, and Federal Circuits suggested that pharmaceutical patents included the right to pay off a potential competitor – Lilly's CEO believed that "such a settlement violated antitrust laws, and it isn't morally right." *Id.*

Barr continued litigating and won the patent case thereby invalidating the Lilly patent. The resulting entry of generic Prozac saved consumers an estimated $2.5 billion. *See Comment of the Generic Pharmaceutical Ass'n in Support of Citizen Pet.*, FDA Docket No. 2004P-0075/CP1, at 3 (filed May 21, 2004), available at http://www.fda.gov/ohrms/dockets/dailys/04/June04/060404/04p-0075-c00003-vol1.pdf.

SUMMARY OF ARGUMENT

Reverse payments follow a common, recurring pattern. Brand and generic manufacturers often enter reverse payment agreements when generic competition is imminent. The payment delays entry by the competitor, generally for years. Indeed, that is precisely the point. The payments are otherwise unnecessary: Hatch-Waxman patent cases can be settled without reverse payments, and, without such payments, the brand and generic would agree to earlier generic entry. To avoid scrutiny, drug companies frequently seek to camouflage the payments as something other than a naked payoff to delay competition.

The brand typically makes a reverse payment to the generic that files the first ANDA, which is the biggest competitive threat. That generic is closest to entering the market. It also has 180 days of marketing exclusivity – the bounty granted by Hatch-Waxman to encourage pharmaceutical patent challenges. Following that pay-off, it may take years for another generic to emerge as a competitor because the subsequent generic must file its own ANDA and resolve any ensuing litigation over the brand's patent. Subsequent generics may have to surmount the bottleneck often created by the first filer's 180-day exclusivity. If subsequent generics represent real competitive threats, the huge monopoly profits of the brand permit it to make multiple reverse payments.

The cases illustrate the inadequacies of the Eleventh Circuit's broad approval of reverse payment agreements. The ruling below virtually impels horizontal competitors to join together to split monopoly profits that would otherwise be competed away to the benefit of consumers. In contrast, a rule regarding reverse payments as *prima facie* anticompetitive would substantially encourage competition. Under such a rule, the parties would be free to reach an alternative no-payment settlement with an earlier entry date or litigate to a conclusion that would lead to earlier generic entry or establish the brand's right to exclude.

Nothing in antitrust law, Hatch-Waxman, or patent law supports the Eleventh Circuit's approach. Antitrust law prohibits horizontal competitors such as the respondents here from agreeing not to compete. By contrast, the Eleventh Circuit relies on standards developed to evaluate *unilateral* conduct that may implicate constitutional First Amendment

concerns – *i.e.*, standards for evaluating fraudulent patent procurement and sham litigation.

Congress enacted Hatch-Waxman to benefit the public by encouraging the fastest possible entry of low-priced generic products. Yet the Eleventh Circuit's ruling turns that statute on its head by permitting it to be used to purchase delays that impose higher prices on consumers.

And, as a matter of patent law, the Eleventh Circuit's ruling impairs innovation by encouraging brand manufacturers to buy protection for their weak patents, which would otherwise be compromised in settlement or eliminated by litigation. That result cannot be reconciled with this Court's precedent, which rejects attempts to broaden patent monopolies, encourages the authoritative testing of such exclusive rights, and safeguards incentives to challenge patents.

The Third Circuit has adopted the correct approach. That court applies a "quick look" rule of reason analysis, treating reverse payments as *prima facie* anticompetitive. That rule is consistent with the purposes of the antitrust and patent laws, yet flexible enough to take account of the circumstances of an individual case. The *prima facie* case may be rebutted by *evidence* that the payment either was made for something other than delay or provided a competitive benefit that could not otherwise have been achieved.

ARGUMENT

I. The Eleventh Circuit's "Scope of the Patent" Test Violates the Policies of Antitrust Law, Hatch-Waxman, and the Patent Act.

a. Competition in the pharmaceutical industry often depends on patent litigation. As the Eleventh Circuit acknowledged, the "huge profits that new drugs can bring frequently attract competitors in the form of generic drug manufacturers that challenge or try to circumvent the pioneer's monopoly in the market." Pet. App. 2a-3a. If permitted by law, a brand name company has every incentive to avoid the risks of patent litigation and pay "the allegedly infringing generic company to delay entering the market until a specified date, thereby protecting the patent monopoly against a judgment that the patent is invalid or would not be infringed by the generic competitor." *Id.* at 3a.

In any other context, such a payment not to compete would be obviously illegal. *See, e.g., Palmer v. BRG of Ga., Inc.*, 498 U.S. 46 (1990); *FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447, 460-61 (1986) (under the rule of reason applicable to most antitrust questions, plaintiffs meet their initial burden by proving either that: (a) the practice has harmed consumers; or (b) the defendant has market power and its conduct is of a type likely to harm consumers).[2] Respon-

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[2] The anticompetitive effects of delaying generic competition are clear. For example, in *Cipro*, before generic entry, Bayer was able to sell Cipro at a price more than twenty times the competitive price. *Ciprofloxacin*, 363 F. Supp. 2d at 523.

dents nonetheless argued, and the court of appeals agreed, that the "patent made all the difference because it meant that the patent holder had a 'lawful right to exclude others' from the market." Pet. App. 17a (quoting *Valley Drug Co. v. Geneva Pharms, Inc.*, 344 F.3d 1294, 1304 (11th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004)).

That was error. The Patent and Trademark Office issues patents in *ex parte* administrative proceedings. Such issuance does not conclusively establish the patent's validity. And, it manifestly does not establish that any generic product infringes the patent. As the Provigil and Prozac cases illustrate, *see supra* pp. 9-10, brand name manufacturers' patents are often found invalid and/or not infringed by would-be generic competitors. *See also* FTC, *Pay-for-Delay*, *supra*, at 3 (estimating that roughly 75% of litigated pharmaceutical patents are found to be invalid or not infringed).

The Eleventh Circuit rested its decision on the abstract notion that a patent represents an unassailable right to exclude competition. But that reasoning ignores the very purpose of Hatch-Waxman to encourage litigation to weed out weak patents that impair competition in the pharmaceutical industry. Hatch-Waxman was intended "to speed the introduction of low-cost generic drugs to market." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012) (citing *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990)). It did so by creating a streamlined application process for generics and granting 180 days of marketing exclusivity to the first generic whose application contains a "Paragraph IV Certification" asserting that the brand's patent "is invalid or will not be infringed by the manufacture,

use, or sale of the [generic] drug." *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). This bounty for entering the market via a patent challenge is a huge incentive to generics to challenge weak or narrow patents. It can be worth hundreds of millions of dollars in profits because the generic can substantially underprice the brand yet still earn a high profit margin given the low cost of the active chemical ingredients in most drugs. If federal law is construed to permit brand companies to buy off the generic companies that Congress deputized to challenge weak patents, the very purpose of the Act to promote generic competition will be subverted.

Nor are reverse payments justified by patent law. Patents are "affected with a public interest." *Precision Instrument Mfg. Co. v. Automotive Maint. Mach. Co.*, 324 U.S. 806, 816 (1945). They are limited exceptions to the general policy of the Sherman Act favoring free competition. *United States v. Masonite Corp.*, 316 U.S. 265, 280 (1942) ("Since patents are privileges restrictive of a free economy, the rights which Congress has attached to them must be strictly construed so as not to derogate from the general law beyond the necessary requirements of the patent statute."). And, it "is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly." *Lear, Inc. v. Adkins*, 395 U.S. 653, 663-64 (1969) (quoting *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892)).

Accordingly, this Court has repeatedly condemned attempts to broaden the physical or temporal scope of the patent monopoly *and* encouraged the authoritative testing of patent validity. *Blonder-Tongue Labs, Inc. v. University of Illinois Found.*, 402 U.S.

313, 343 (1971). *See also Lear*, 395 U.S. at 670 (patentee cannot "muzzle[ ]" those who otherwise have an "economic incentive to challenge the patentability of an inventor's discovery"). Consistent with these principles, this Court has held that patent law does not confer a right to expand the exclusionary power of a patent through private contract.[3]

Particularly relevant here, the Court has also held that ownership of a patent does not preclude antitrust liability.[4] Thus, competitors are properly held liable for violating the antitrust laws, notwithstanding that their agreement seeks to settle patent litigation. *Masonite*, 316 U.S. at 279 (denouncing patent holder's attempt "under the guise of his patent monopoly not merely to secure a reward for his invention but to secure protection from competition which the

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[3] *See, e.g., Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 136-37 (1969) (a patentee "may not use the power of his patent to levy a charge for making, using, or selling products not within the reach of the monopoly granted by the Government"); *Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 668 (1944) ("If such an expansion of the patent monopoly could be effected by contract, the integrity of the patent system would be seriously compromised."); *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 492 (1942) ("the public policy which includes inventions . . . forbids the use of the patent to secure an exclusive right or limited monopoly not granted by the Patent Office and which it is contrary to public policy to grant").

[4] *See, e.g., Masonite*, 316 U.S. at 277 ("The owner of a patent cannot extend [its] statutory grant by contract or agreement. A patent affords no immunity for a monopoly not fairly or plainly within the grant."); *Standard Sanitary Mfg. Co. v. United States*, 226 U.S. 20, 49 (1912) ("Rights conferred by patents are indeed very definite and extensive, but they do not give any more than other rights a universal license against positive prohibitions.").

patent law unaided by restrictive agreements does not afford"). *See also United States v. Singer Mfg. Co.*, 374 U.S. 174, 200 (1963) (White, J., concurring) (collusion to prevent prior art from being presented to patent office should be "presumptively bad" because "patent laws do not authorize, and the Sherman Act does not permit, such agreement between business rivals to encroach upon the public domain and usurp it to themselves").

b. The Eleventh Circuit's "scope of the patent" test cannot be reconciled with this Court's precedents. Despite this Court's efforts to keep patents within their prescribed temporal *and* physical boundaries, the only "scope" that the test considers is whether the settlement bars entry after expiration of the patent.[5] It otherwise assumes the generic to be within the substantive scope of the patent based solely on the brand's allegations. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213-14 (2d Cir. 2006). *See also* Michael Carrier, *Why the "Scope of the Patent" Test Cannot Solve the Drug Patent Settlement Problem*, 16 STAN. TECH. L. REV. 1, 5-6 (2012) (criticizing "scope of the patent" test as it has developed for assuming the validity issues "central to the determination of antitrust analysis").

As a result, the "scope of the patent" test permits brands to purchase from the generics a further period of exclusivity by avoiding authoritative judicial determinations of validity and infringement. As the Second Circuit recognized, the approach creates the

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[5] The name of the test is highly misleading in that it relies entirely on the brand's allegation and makes no assessment of the patent's substantive scope.

"troubling dynamic" in which brand name manufacturers with the weakest patents – even if "fatally weak" – are most likely to secure the greatest immunity from competition by paying off their competitors. *Tamoxifen*, 466 F.3d at 211-12. It protects "intellectual property, not on the strength of a patent holder's legal rights, but on the strength of its wallet." *K-Dur*, 686 F.3d at 217 (citing C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1614 (2006)).

Affirmance of the Eleventh Circuit would cause reverse payment agreements to further proliferate.[6] The "scope of the patent" test has no meaningful limits. It permits brands to pay as much as they wish to as many generics as they wish to block generic competition right up to the date of patent expiration. Because such payments preserve the brand's monopoly, the brand and generic profit more from them than they would from competition. As a result, if generally permitted, reverse payments will displace more competitive settlements as well as litigated judgments.

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[6] In fact, the number of reverse payments would likely explode. Reverse payments have already dramatically increased as a result of just three permissive appellate opinions even though this Court never ruled on them, pharmaceutical executives publicly expressed concerns about their legality, and three other appellate decisions called their legality into doubt. *See In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 907 (6th Cir. 2003) (*per se* illegality of reverse payments), *cert. denied*, 543 U.S. 939 (2004); *Andrx Pharm. Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 813 (D.C. Cir. 2001) (reverse payment undoubtedly "harms consumers"), *cert. denied*, 535 U.S. 931 (2002); *K-Dur*, 686 F.3d at 218 (reverse payments *prima facie* anticompetitive).

There will be little rational economic or legal reason for generics to ever settle without a reverse payment or to litigate Hatch-Waxman cases to a final judgment. Companies like Lilly facing generic competition will be unwilling to subject their multi-billion dollar drug franchises to the litigation risk of losing exclusivity if they may avoid that risk by sharing monopoly profits with their competitors. *See supra* p. 10 (Prozac). Nor will they need to reach early-entry settlements taking that risk into account because they can simply pay to delay generic entry until the end of the patent term. Weak and otherwise "fatally weak" patents will continue to block competition, and consumers will pay much higher prices.

The public will suffer from lessened innovation caused by preserving weak patents and private agreements extending patents beyond their substantive terms.[7] *See generally United States v. Aluminum*

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[7] The Eleventh Circuit suggested that the high cost to develop new brand products somehow justifies collusive payments to delay competition. Pet. App. 2a. But patent holders are not exempt from the antitrust laws. *See supra* note 4. Moreover, the development costs cited by the Eleventh Circuit (and brand companies) have been severely criticized as applicable only to a few of the most expensive drugs. *See* MARCIA ANGELL, THE TRUTH ABOUT DRUG COMPANIES 42 (2004). The methodology behind the estimates has been criticized for *inter alia*: (1) calculating "opportunity costs" based on hypothetical returns on alternate investments for R&D expenditures; (2) failing to recognize that much of the initial research for new chemical entities is performed by the National Institutes of Health or universities; and (3) ignoring R&D-related tax credits received by pharmaceutical firms. *See id.* at 44-65. *See generally* MERRILL GOOZNER, THE $800 MILLION PILL: THE TRUTH BEHIND THE COST OF NEW DRUGS (2004); Donald W. Light & Rebecca Warburton,

Co. of Am., 148 F.2d 416, 427 (2d Cir. 1945) (L. Hand, J.) (observing that "immunity from competition is a narcotic, and rivalry is a stimulant, to industrial progress; [ ] the spur of constant stress is necessary to counteract an inevitable disposition to let well enough alone").

Pharmaceutical patents often cover minor formulations that are not critical to a drug's biological activity. As a result, like Upsher in *K-Dur*, generic competitors can often design around those patents by developing new formulations. *See supra* p. 4. Under the patent laws, such innovations can be excluded only if the brand proves infringement, but reverse payments allow brands to pay to convert a mere allegation of infringement into guaranteed exclusivity.

Without reverse payments, earlier generic entry could occur in several ways. A generic manufacturer might launch upon expiration of the thirty-month stay ("at risk" because the litigation is unresolved) or after final judgment establishing the patent to be invalid or not infringed. *See supra* pp. 9-10 (judgments in *Provigil* and *Prozac*). Alternatively, the parties may settle by negotiating an earlier no-payment entry date or agreeing to licensed generic entry. An arm's length license negotiated in accordance with the value that the parties put on their respective claims does not ordinarily violate the antitrust laws. *See Standard Oil Co. v. United States*, 283 U.S. 163, 171 (1931).

Demythologizing the High Costs of Pharmaceutical Research, BIOSOCIETIES, Mar. 2011, at 34-50.

A reverse payment settlement is unlike a license agreement or a compromise of patent damages. In both of those cases, the accused infringer benefits by selling its product in competition with the patent holder. In the absence of a reverse payment, a generic will negotiate to enter the market as early as possible or remain on the market for as long as possible consistent with its view of the strength of the patent (and the brand will seek to minimize that time consistent with its own views of patent strength). In contrast, a brand makes a reverse payment to a generic to compensate it for staying off the market and *not* making sales.[8] *See K-Dur*, 686 F.3d at 218 (agreeing that "[a]bsent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise" (quoting

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[8] Pharmaceutical manufacturers argue that reverse payment settlements are procompetitive if they permit generic entry before patent expiration. Such arguments necessarily assume that the brand is entitled to exclude the generic for the full term of the patent even though it paid to avoid just such a determination. No such assumption is warranted. Compared to alternate outcomes (*e.g.*, a no-payment settlement or the risk adjusted expected outcome of the litigation), reverse payments reduce competition. Moreover, the "scope of the patent" test, if adopted, would allow brand companies to pay generics to stay off the market right up to the date of patent expiration. The test as it has developed contains no limiting principle. While the legal standard has been in flux, manufacturers have exercised some restraint in agreeing to permit generic entry before patent expiration. However, were the Court to adopt the "scope of the patent" test as the law of the land, nothing in the test would prevent brands from buying exclusion for the entire term of the patent.

In re Schering-Plough Corp., 136 F.T.C. 956, 988 (2003)). *Cipro* proves this logic. There, the settlement agreement included an optional license that would have allowed generic entry with a royalty, but Bayer chose to make additional reverse payments to delay entry beyond the agreed-upon licensed entry date. *See supra* pp. 6-7.

In the absence of a reverse payment, the interests of the generic and consumers are aligned because both benefit by early sales of a low-priced generic. In contrast, when a generic accepts compensation to delay competition, it profits by agreeing not to make such sales. As a result, consumers are robbed of the benefits that they would have otherwise received. *K-Dur* 3d Cir. App. A-3158. This severance of interests between the potential entrant and consumers is the hallmark of anticompetitive conduct. *Premier Elec. Constr. Co. v. Nat'l Elec. Contractors Ass'n, Inc.*, 814 F.2d 358, 369-70 (7th Cir. 1987). *See also* XII HERBERT HOVENKAMP, ANTITRUST LAW ¶ 2046c, at 343 (3d ed. 2012) (explaining difference between reverse payment and licensed entry).

c. The fraudulent procurement and sham litigation exceptions to the "scope of the patent" rule do not address the anticompetitive effect of reverse payments. These standards distinguish unprotected unilateral conduct actionable under the antitrust laws from protected conduct (which may be within the First Amendment). *See Professional Real Estate Investors, Inc., v. Columbia Pictures Indus., Inc.*, 508 U.S. 49 (1993) (sham litigation as Section 2 violation); *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965) (fraudulent patent procurement as Section 2 violation). They do not address the anticompetitive effects of collusive agree-

ments in which entrenched monopolists pay potential competitors not to compete. Such joint conduct has always been "judged more sternly" than unilateral conduct under antitrust law. *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 768 (1984). *See also Alvord-Polk, Inc. v. F. Schumacher & Co.*, 37 F.3d 996, 1000 (3d Cir. 1994), *cert. denied*, 514 U.S. 1063 (1995).

II. There Is No Merit to the Justifications Offered in Support of the Eleventh Circuit's Rule Broadly Approving Reverse Payment Agreements.

The litigated challenges to reverse payment agreements demonstrate that the justifications offered in support of the Eleventh Circuit's "scope of the patent" test have no merit. To the extent that the circumstances of a particular case provide special justification for a reverse payment, the courts are well equipped to address such a case under the "quick look" rule of reason, which is not a rule of *per se* illegality. The *prima facie* case established by evidence of a reverse payment may be rebutted by showing that the payment was made for a reason other than delay or offered a pro-competitive benefit that could not be achieved in the absence of the reverse payment. *K-Dur*, 686 F.3d at 218. Unlike the "scope of the patent" test, the "quick look" rule of reason does not make counterfactual assumptions. It acknowledges the unmistakable anticompetitive effects of reverse payments, but allows them to be rebutted with specific evidence.

A. A Patent's Presumptive Validity Does Not Confer a Right to Conspire to Delay Competition.

The principal justification for the Eleventh Circuit's ruling is that the law presumes issued patents to be valid. *See* 35 U.S.C. § 282; *Schering*, 402 F.3d at 1066; *Tamoxifen*, 466 F.3d at 208-09 & n.22; *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1337 (Fed. Cir. 2008).

But the presumption of validity is not an ironclad "right to exclude." It is a *rebuttable* presumption that may be challenged by accused infringers. Indeed, it is only a "procedural device and is not a substantive right of the patent holder." *K-Dur*, 686 F.3d at 214 (citing *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983)). *See also Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 625 F.3d 779, 781 (2d Cir. 2010) (Pooler, J., dissenting) (finding "no basis for treating [the presumption of validity] as virtually conclusive and allowing it to serve as a substantive basis to limit the application of the Sherman Act").

The presumption of validity has never before entitled a patentee to exclude a competitor. In preliminary injunction proceedings, the patentee must establish the likelihood of a patent's validity; it may not rest on the presumption. *Nutrition 21 v. United States*, 930 F.2d 867, 869 (Fed. Cir. 1991). *See also Reebok Int'l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1556 (Fed. Cir. 1994). Courts frequently deny preliminary injunctions on the ground that, until there is a judicial finding of validity and infringement, the alleged infringer has a "right to compete." *See, e.g., Illinois*

Tool Works, Inc. v. Grip-Pak, Inc., 906 F.2d 679, 684 (Fed. Cir. 1990).

Even after entry of a final judgment of infringement, a patentee is not automatically entitled to the kind of exclusivity purchased with reverse payments. In *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 393 (2006), this Court held that a prevailing patentee must satisfy the traditional requirements for equitable relief before such exclusion is ordered.

There is no basis in law or logic to give greater force to the rebuttable presumption of validity in this context. Many pharmaceutical patents subject to reverse payments are of low quality or cover minor features not critical to the biological properties of the drug. *See* XII HERBERT HOVENKAMP, ANTITRUST LAW, *supra*, at 345. In *Provigil*, a generic that was not paid off established that the patent was invalid and not infringed. *See supra* p. 9. In *Prozac*, after Lilly refused to make a reverse payment, the district court found the patent invalid. *See supra* p. 10. *See also Generic Pharmaceuticals Marketplace Access and Consumer Issues: Hearing Before the Senate Commerce Comm.*, 107th Cong. (Apr. 23, 2002) (statement of Kathleen D. Jaeger, President & CEO, Generic Pharmaceutical Ass'n) at 12 (warning of questionable brand patents).

Reliance on the presumption of validity is "particularly misguided" to justify reverse payments made to generic competitors that seek to introduce non-infringing alternatives. *K-Dur*, 686 F.3d at 214. A patent's "validity" says nothing at all about a right to exclude a competitor that has sought to avoid the patent by designing around it, as in *K-Dur* (lower viscosity ethylcellulose) and *Provigil* (larger particle size). *See supra* pp. 4, 9. In such circumstances, the

patentee (the brand) must prove infringement by the competitor (the generic).[9] In broadly approving reverse payments on the basis of the presumption of validity, the Eleventh Circuit has repeatedly failed to understand the critical difference between proof of invalidity and infringement. *See Schering*, 402 F.3d at 1066-67 (incorrectly asserting that Schering's patent gave it the right to exclude until the generic manufacturers "proved either that the '743 patent was invalid or that their products . . . did not infringe Schering's patent"); Pet. App. 24a (repeating error from *Schering*).

B. The Anticompetitive Effects of Reverse Payments Are Not Ameliorated by the Prospect of Subsequent Generic Entry.

Some courts have asserted that the market will quickly correct the anticompetitive effects of reverse payments. According to the Eleventh Circuit, a patent holder may be able to "escape the jaws of competition by sharing monopoly profits with the first one or two generic challengers [but] those profits will be eaten away as more and more generic companies en-

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[9] *See, e.g., Lehigh Valley R.R. Co. v. Mellon*, 104 U.S. 112, 119 (1881) (infringement "cannot be presumed"); *Imhaeuser v. Buerk*, 101 U.S. 647, 662 (1879) ("burden to prove infringement never shifts"); *Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665, 678 (Fed. Cir. 2008) ("the burden of proof as to infringement remains on the patentee"), *cert. denied*, 129 S. Ct. 1917 (2009). In the infringement analysis, the patent holder's construction of its patent is "entitled to no deference" and may be rejected entirely. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 983 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996).

ter the waters by filing their own paragraph IV certifications attacking the patent." Pet. App. 36a. *See also Tamoxifen*, 466 F.3d at 195.

On that logic, brand manufacturers are making a terrible miscalculation, handing over tens of millions of dollars to generic competitors, when others will promptly take their place in the market. In fact, the brands are smarter than that. The court's simplistic analysis ignores the reality of pharmaceutical markets.

The complex regulatory scheme for pharmaceutical patents means that, by paying off one ANDA filer, a patent owner may be able to delay entry by subsequent generic challengers for years. *See* HERBERT HOVENKAMP ET AL., IP AND ANTITRUST § 15.3a1(C), at 15-50 (Supp. 2012). *See also* C. Scott Hemphill, *Paying for Delay*, *supra*, 81 N.Y.U. L. REV. at 1586. The entry barriers for subsequent generics include the substantial cost and time to develop the generic and to prepare and file an ANDA; the cost and time to gain FDA approval; the Hatch-Waxman automatic thirty-month stay, 21 U.S.C. § 355(j)(5)(B)(iii); and the first filer's 180 days of exclusivity, *id.* § 355(j)(2)(A)(vii)(IV). *K-Dur* 3d Cir. App. A-3309-10. In *Tamoxifen*, the brand paid off the generic manufacturer in March 1993, while awaiting a Federal Circuit ruling. *See Tamoxifen*, 466 F.3d at 193. Subsequent challengers did not obtain a Federal Circuit ruling until April 1997 – more than four years later. *See Zeneca Ltd. v. Novopharm Ltd.*, 111 F.3d 144 (Fed. Cir. 1997). And, every day that a generic for a multi-billion-dollar-a-year brand is delayed equals millions of dollars of harm to consumers.

In addition, subsequent generic filers do not have the same motivations to litigate as the first filer. The

first generic is substantially more likely to incur the costs of litigating against the brand because if successful it receives the 180 days of marketing exclusivity that Hatch-Waxman provides as a bounty to spur such challenges. Later challengers do not get the benefit of that exclusivity. *See K-Dur*, 686 F.3d at 215; *Arkansas Carpenters*, 604 F.3d at 109-10. *Contra Tamoxifen*, 466 F.3d at 214 (incorrectly suggesting that exclusivity would roll over to subsequent challengers).

As a result, subsequent generics may not have the time or the motivation to press expensive and time-consuming legal theories. Indeed, in *Cipro*, Bayer prevailed against subsequent generic manufacturers pursuing different theories after paying the first generic manufacturer almost $400 million and disabling its counsel from representing any subsequent generic. *See supra* pp. 7-8.

Even when another generic can effectively enter the market, however, the Eleventh Circuit's decision leaves the brand free to use its huge monopoly profits to pay off subsequent competitors. Indeed, the cases show that the brand can pay off multiple generic entrants. Here and in *K-Dur*, the brand paid off two generics. *See supra* p. 5. And, in *Provigil*, the brand paid off *four* generics. *See supra* p. 8.

C. Reverse Payments Are Not Necessary to Settle Hatch-Waxman Cases.

Courts have sought to justify the "scope of the patent" test on the ground that reverse payments are necessary to settle Hatch-Waxman cases. *See* Pet. App. 33a; *Tamoxifen*, 466 F.3d at 212; *Ciprofloxacin*, 544 F.3d at 1333. That assertion is somewhat ironic given that drug manufacturers often deny making

reverse payments, claiming the payments to be compensation for benefits other than delayed generic entry such as backup supply arrangements or co-promotion services (*Watson*) or license fees for other drugs (*K-Dur*).

In any event, the parties can almost always settle Hatch-Waxman cases without reverse payments. When the FTC announced in 2000 that it would aggressively prosecute reverse payments, pharmaceutical manufacturers stopped using them. But they continued to settle Hatch-Waxman patent cases, using instead the tools litigants employed in patent litigation for decades – principally, early-entry licenses. Statement of FTC Commissioner J. Leibowitz to the Special Committee on Aging of the U.S. Senate on Barriers to Generic Entry 13-14 (July 20, 2006), available at http://www.ftc.gov/os/2006/07/P052103BarrierstoGenericEntryTestimonySenate07202006.pdf. The use of reverse payments dramatically increased after lower court rulings broadly immunizing them from antitrust liability. FTC FY 2012 Overview, *supra*, at 2 (reporting record number of potential pay-for-delay deals in 2012).

In Europe, after the European Commission seriously questioned their legality, reverse payments declined significantly. *See* European Commission, 3d Report on the Monitoring of Patent Settlements (period: January - December 2011) ¶ 45 (July 25, 2012), available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report3_en.pdf. Notably, the increased scrutiny of reverse payments did not impair the ability of parties to settle patent litigation: the number of pharmaceutical patent settlements has actually increased in Europe. *Id.* ¶ 50.

Brand and generic manufacturers can almost always reach a settlement in which the generic receives an earlier entry date rather than a payment. Generic entry has a predictable financial impact on brand and generic manufacturers. As a result, it is a relatively simple matter for a brand and generic to reach an arm's length agreement setting an entry date that reflects their independent evaluations of the risks of litigation. Such an agreement is not anticompetitive because the generic profits by entering the market rather than dividing the brand's monopoly profits.

In *K-Dur*, *amici*'s expert demonstrated that reverse payments are necessary to achieve an efficient settlement in only one-half of one percent of all Hatch-Waxman cases, and that *K-Dur* itself could have been settled without such a payment. *K-Dur* 3d Cir. App. A-3164; Leffler & Leffler, *Settling the Controversy*, *supra*, 21 RESEARCH IN LAW & ECON. at 486. Indeed in *Cipro*, the parties actually agreed upon a royalty-bearing license as an alternative to continued reverse payments. Bayer elected to make $349 million in additional payments rather than allowing earlier licensed generic entry. *See supra* pp. 6-7.

D. Reverse Payments Are Not Warranted As a "Natural By-Product" of the Hatch-Waxman Regime.

Drug companies argue that reverse payments must be tolerated as a "natural by-product" of Hatch-Waxman, which purportedly increased the generic's leverage to negotiate a favorable settlement from the brand. *Tamoxifen*, 466 F.3d at 206; *Schering*, 402 F.3d at 1074. The argument has no merit.

Hatch-Waxman does not increase the generic's settlement leverage. Hatch-Waxman grants the

brand the option to confer such leverage on the generic. It allows the brand to sue the generic based on its ANDA without waiting for the generic to introduce its generic product. 21 U.S.C. § 355(j)(5)(B)(iii). The brand benefits from such a suit because it triggers an automatic thirty-month stay of generic entry, but, as a consequence, the generic gets to challenge the brand's patent without entering the market and subjecting itself to the threat of damages.

The brand need not confer this leverage on the generic. Instead, it may wait until the generic enters the market and files a traditional infringement suit. In that case, the generic is subject to ordinary infringement damages and enjoys no increased settlement leverage. *See* 35 U.S.C. § 271(a). As brand manufacturer Merck acknowledged in its pending petition for certiorari, the patentee has no reason to offer a reverse payment in such a traditional infringement suit. Petition of Merck & Co. at 5-6 (Aug. 2012), in *Merck & Co., Inc. v. Louisiana Wholesale Drug Co.*, No. 12-245. Accordingly, any increased generic "leverage" under Hatch-Waxman results entirely from the brand's decision to institute an anticipatory suit.

In any event, any increased leverage conferred by Hatch-Waxman should be a reason to safeguard that leverage against collusion, not to exempt it from antitrust scrutiny. For example, Congress might adopt a statutory scheme to incentivize construction of plants in a new industry in an effort to spur competition and lower prices. If suppliers responded to the resulting competition by colluding to keep prices high, their price-fixing agreement would be unlawful, not excused as a "natural by-product" of Congress' effort to increase price competition. *See* Herbert Hovenkamp,

Anticompetitive Settlement of Intellectual Property Disputes, 87 MINN. L. REV. 1719, 1758-59 (2003); C. Scott Hemphill, *Paying for Delay*, *supra*, 81 N.Y.U. L. REV. at 1577 (that exclusion payments are "not unexpected" under the Act "in no way justifies" them).

Congress could adopt a special antitrust regime that approved reverse payments eliminating pharmaceutical competition, but it has done no such thing. To the contrary, the very point of Hatch-Waxman was to encourage generic competition, in order to benefit consumers. *See* H.R. Rep. No. 98-857(I), at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647-48 (Act's purpose is "to make available more low cost generic drugs"). And, the statute confers benefits only on manufacturers that actually enter the market. *See* 21 U.S.C. § 355(j)(5)(B)(iv). "Although it is true that the first to file an ANDA is permitted to delay marketing as long as it likes, the statutory scheme does not envision the first applicant's agreeing with the patent holder of the pioneer drug to delay the start of the 180-day exclusivity period." *Andrx*, 256 F.3d at 809. *See also Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1072 (D.C. Cir. 1998) (collusion between brand and generic manufacturers is "at odds with Congress's apparent purposes, in enacting [the Act], of rewarding innovation and bringing generic drugs to market quickly"). It is therefore not surprising that the co-authors of Hatch-Waxman have denounced reverse payments as "appalling," 148 Cong. Rec. S7565-01 (daily ed. July 30, 2002) (remarks of Sen. Hatch), and as "a grossly anticompetitive abuse . . . of the generic drug approval process," 146 Cong. Rec. E1538-02 (daily ed. Sept. 20, 2000) (remarks of Rep. Waxman).

III. The Court Should Not Address Damage Issues in This Case.

As the Solicitor General explains, this case in which the FTC seeks injunctive relief does not raise any issue regarding the methodology for proving damages in a private antitrust suit. Pet. Br. 55 n.11. To the extent reverse payment cases raise questions related to antitrust damages, the Court should leave those issues to be addressed in a case in which they actually arise.

Causation in private damage actions is an intensely factual issue that should not be resolved in the abstract. *Story Parchment Co. v. Paterson Parchment Paper Co.*, 282 U.S. 555, 566 (1931). The issue is whether the antitrust violation is a "material cause" of plaintiffs' injury. *Zenith*, 395 U.S. at 114 n.9. No defendant is entitled to defend on the ground that its own conduct has made it difficult to prove what would have happened but for its wrongful conduct. III HERBERT HOVENKAMP ET AL., ANTITRUST LAW, *supra*, at ¶ 651c (3d ed. 2012).

The precise evidence required to prove damages caused by a reverse payment – *i.e.*, that a generic manufacturer would have entered the market earlier in the absence of a reverse payment – is likely to vary from case to case. Plaintiffs may use basic principles of economics and the expected impact of generic entry (including the companies' own forecasts) to estimate the generic entry date in an alternative no-payment settlement. *See, e.g.*, K-Dur 3d Cir. App. A-3158-64. Alternatively, nothing would prohibit plaintiffs in an appropriate case from offering evidence of the outcome of the patent litigation but for the reverse payment. *Id.* at A-3179. Courts and juries in legal mal-

practice cases regularly consider such evidence when they decide who would have won the underlying litigation absent attorney error. *See, e.g.*, *First Union Nat'l Bank v. Benham*, 423 F.3d 855, 860 (8th Cir. 2005). *See also Tamoxifen*, 466 F.3d at 229 (Pooler, J., dissenting). Or plaintiffs may elect to prove that in the absence of the reverse payment the generic would have entered "at risk" upon the expiration of the thirty-month stay. *See, e.g.*, *Cardizem*, 332 F.3d at 911 (finding antitrust injury because "a trier of fact may well find that the [brand's] $89 million payment *renders incredible* the defendants' claim that [the generic] would have refrained from marketing [during the patent litigation] simply because of its fear of infringement damages") (emphasis added).

There may be other ways to establish causation on the facts of particular cases. These issues are not presented by the FTC's complaint and should be left for further development by the lower federal courts in appropriate cases.

CONCLUSION

The Court should reverse the judgment of the Court of Appeals for the Eleventh Circuit in this case and hold that reverse payments are *prima facie* anti-competitive.

Respectfully submitted,

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AMICUS CURIAE BRIEF

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Petitioner,

v.

ACTAVIS, INC., *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

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IDENTITY AND INTEREST OF *AMICI CURIAE*[1]

All parties consent to the filing of this brief. The Mediation and Negotiation Professionals *Amici* are mediation professionals or professors with extensive experience in mediation and negotiation, and some have written extensively on these subjects. Their principal interest in this case is in the preservation and advancement of sound mediation and negotiation principles in the dispute resolution process. *Amici* file this brief because they believe that the approach to settlement advanced by the FTC will undermine the policy favoring settlements by reducing the tools mediators and negotiators have to resolve disputes. The inflexible rule proposed by the FTC tends to discourage settlements, impair their integrity, and reduce mutual settlement value. Reversal of the decision of the Eleventh Circuit will have a chilling effect on achieving effective and value-enhancing resolution of their disputes.

Amicus Robert C. Bordone is the Thaddeus R. Beal Clinical Professor of Law at Harvard Law School and the founding Director of the Harvard Negotiation & Mediation Clinical Program. His research interests include the design and implementation of dispute resolution systems,

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1. Pursuant to Supreme Court Rule 37.6, counsel for *amici* represents that no counsel for a party authored this brief in whole or in part and that none of the parties or their counsel nor any other person or entity other than *amici*, its members, or its counsel, made a monetary contribution intended to fund the preparation or submission of this brief. Pursuant to Rule 37.3(a), counsel for *amici* represents that all parties have consented to the filing of the brief. Letters reflecting their consent are on file with the Clerk.

the development of a problem-solving curriculum in law schools, and ADR ethics. Professor Bordone is the co-author of two books and has published numerous articles in leading dispute resolution journals.

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This brief represents the views of the *amici* and does not necessarily reflect the views of their employers or any other group or organization with which they may be affiliated. Institutions are listed for identification purposes only.

SUMMARY OF THE ARGUMENT

The FTC's approach to patent disputes would reduce the number of successful settlements and destroy value available to both patent holders and generic manufacturers. By presuming illegality when patent settlements exchange multiple forms of consideration, the FTC would require parties to adopt a zero-sum, distributive method of negotiating on the single variable of the patent's remaining period of exclusivity. *Amici*, who mediate disputes, research and write about conflict management, and teach negotiations skills, submit this brief to inform the Court that modern negotiation theory and practice consider this approach to be artificially limited and inappropriate for complex disputes like the one currently before the Court.

ARGUMENT

I. ANTITRUST TREATMENT OF PATENT SETTLEMENTS SHOULD BE CONSISTENT WITH LONGSTANDING JUDICIAL POLICIES AND STRUCTURES THAT ENCOURAGE SETTLEMENTS.

Litigation of any kind, including the simplest tort dispute, creates cost, uncertainty, and a "bilateral monopoly" problem in which each party can only settle with the other party, and no single settlement is necessarily the most appropriate or efficient. *In re Hoskins*, 102 F.3d 311 (7th Cir. 1996). To encourage dispute resolution and to reduce court congestion, this Court has favored private settlements (*E.g.*, *McDermott, Inc. v. AmClyde*, 511 U.S. 202, 215 (1994)) and enforced rules that foster the repose of litigation (*E.g.*, *Nevada v. United States*, 463 U.S. 110, 129 (1983)). Lower courts have adopted a variety of structures and policies to encourage or require mediation at various points in most cases, in the hope of causing private settlements.

The Eleventh Circuit's rule properly precludes settlements that include anticompetitive effects beyond the patent's inherent exclusionary potential. Pet. App. 28a. The FTC's proposed approach would go beyond that rule and limit the parties to negotiating and exchanging only one form of consideration in their settlement contracts --agreed shortening of the patent's remaining period of exclusivity. The FTC's rule of presumptive illegality would be contrary to the Court's longstanding approach to encouraging settlements because it is contrary to modern negotiating theory about how to best accomplish dispute resolution.

II. RESTRICTING PATENT NEGOTIATIONS TO A SINGLE VARIABLE WILL REDUCE THE NUMBER AND QUALITY OF SETTLEMENTS.

A. Negotiating Theory Generally Recommends Increasing the Number of Interests Discussed To Reach Settlement.

The FTC's approach would restrict patent disputants to discussing only the duration of the remaining period of patent exclusivity. Reducing the negotiation to that single variable necessitates zero-sum, distributive bargaining in which a gain for one party translates to a loss for the other. Over four decades of negotiation research and literature have rejected distributive bargaining as inadequate for complex disputes.

Negotiators and mediators often purposefully *widen* rather than *narrow* the variables in play, to increase the likelihood of finding a settlement and increasing total value. *See generally* Roger Fisher, William Ury & Bruce Patton, *Getting to Yes* 56 (3d ed. 2011) (hereinafter "*Getting to Yes*"). "[T]he more alternative courses of action considered by decision makers, the better the payoff to that decision is likely to be." Howard Raiffa et al., *Negotiation Analysis: The Science and Art of Collaborative Decision Making* 402 (2002). More solutions, and more value, can be produced by integrative (or "problem-solving") negotiation. Michael L. Moffitt, *Pleadings in the Age of Settlement*, 80 Ind. L. J. 727, 737-746 (2005).

Judges regularly witness what the dispute resolution literature predicts. "A negotiation is more likely to be successful when there are several issues to be resolved

("integrative bargaining") rather than just one, because it is easier in the former case to strike a deal that will make both parties feel they are getting more from peace than from war." *Duffy Tool & Stamping, L.L.C. v. NLRB*, 233 F.3d 995, 998 (7th Cir. 2000) (citing Raiffa, *The Art and Science of Negotiation* 97-103, 131-32). *Duffy* offered the example of a labor negotiation: if that negotiation is prohibited from going beyond wages, it reduces the probability of agreement and the total potential value of such an agreement. Adding other issues, such as a dues checkoff issue or a no-strike clause, changes the negotiation from a zero-sum game and opens avenues for trade toward a value maximizing settlement. *Duffy*, 233 F.3d at 998.

The best way to maximize value is to exploit shared and differing interests. Shared interests are interests that both sides have in common, such as reducing transaction costs or implementation problems. If the parties are not artificially constrained, they can agree to pursue them together. Differing interests may matter greatly to one side and little to the other, enabling the parties to make high-value, low-cost trades. Such interests include differences in priorities, differences in timeframes, differences in prediction, differences in risk tolerance, and differences in capabilities. Moffitt, *Disputes as Opportunities to Create Value*, *in* The Handbook of Dispute Resolution 173, 176 (Moffitt & Robert C. Bordone, eds., 2005).

While the idea of creating value through differences is "counterintuitive to many negotiators," dispute resolution scholars have explained that the "truth is that differences are often more useful than similarities in helping parties reach a deal. Differences set the stage for possible gains

through trade, and it is through trade that value is most commonly created." Robert H. Mnookin, Scott R. Peppet & Andrew S. Tulumello, *Beyond Winning: Negotiating to Create Value in Deals and Disputes* 14 (2000). Multi-dimensional negotiation allows the parties to "exploit the gains of trade inherent in their different valuation of the issues." Rafael Hortala-Vallve et al., *An Experimental Comparison Between Free Negotiation and a Multi-issue Point Mechanism* 2 (Dep't of Gov't, London Sch. of Econ. and Pol. Sci., Monograph, 2010), *available at* http://www.coll.mpg.de/Download/llorente/negotiation.pdf.

By purposefully widening the negotiation to seek exchanges "that are relatively easy for one party to give and valuable for the other party to get" and by joining "core issues with complementary issues," trading is better facilitated. David A. Lax & James K. Sebenius, *3-D Negotiation: Powerful Tools to Change the Game in Your Most Important Deals* 42 (2006) (hereinafter "*3-D Negotiation*"). "It's the *differences* of interests that create joint gains." *Id.* (emphasis added).

B. Integrative Negotiation Is Particularly Appropriate For Patent Cases.

This integrative negotiating approach is especially valuable in patent litigation, which offers innumerable opportunities for good negotiators to follow prevalent negotiating advice to "[s]eek other value-creating differences." *3-D Negotiation* at 42. Such trades need not extend beyond the Eleventh Circuit's recognition of the exclusionary potential of the original patent. This case included agreements to provide backup manufacturing capacity and to promote the product to primary care

physicians and urologists. *See* Second Amended Complaint ("Complaint") ¶¶ 66, 74, 77, J.A. 46, 48, 49. Dozens of variables and interests are likely to be available to negotiators over the lengthy duration of most patent cases. The values placed on those interests by the parties will differ, despite the belief by the FTC and its *amici* that limiting negotiations to the exclusivity period will somehow cause the parties to better approximate the real strength, merit, or likely "success" of the patent.[2]

In reality, parties' perceptions of patent *merit* and litigation "success" are likely to differ at any point during a patent case, are likely to change over the course of the litigation, and are only one of the many interests and different valuations that can drive multidimensional settlements. The parties' differing risk preferences, liquidity preferences, litigation tolerance, and other interests can be powerful influences in finding a trade that justifies settlement. Studies show that parties generally overstate their prospects for success,[3] and that even a judicial declaration of patent "merit" or litigation success

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2. *See Brief for 118 Law, Economics, and Business Professors and the American Antitrust Institute in Support of Petitioner* at 12. ("An agreement concerning the generic entry date, without any cash payment, will normally reflect the odds of the parties' success in patent litigation...").

3. George Loewenstein et al., *Self-serving Assessments of Fairness and Pretrial Bargaining*, J. Legal Stud. 135, 140-141 (1993) (studies and empirical evidence of self-serving bias and overestimates of a party's chances of success); Vivian Berger et al., *Summary Judgment Benchmarks for Settling Employment Discrimination Lawsuits*, 23 Hofstra Lab. & Emp. L.J. 45, 46 (2005) (noting that at the outset of talks, parties' estimates of their probabilities of victory "may be as great as 150%").

is likely to be reversed almost half the time.[4] Limiting negotiations to zero-sum adjustments of the exclusivity period would ignore the opportunity for trading that is presented by the parties having so many different interests and such different perceptions of their values.

From "small" settlement contract details about how to enforce the settlement (choice of venue, choice of law, use of arbitration), to seemingly "larger" issues about marketing services, backup capacity, or confidentiality, the very act of artificially labeling these considerations as "large" or "small" ignores the negotiating lesson that trade is facilitated precisely by allowing parties to give these issues different levels of importance, to trade their perceived values in ways that facilitate settlements, and to express their trades in multiple currencies of exchange or forms of consideration.

CONCLUSION

Integrative negotiation is especially appropriate for patent cases because of their complexity and uncertainty. This uncertainty creates an ideal environment for effective integrative negotiation. In the context of a judicial system that otherwise encourages settlements, otherwise values the repose provided by such settlements, and inherently relies upon consensual negotiation to reduce dockets and create mutual value, the FTC's proposed zero-sum construct should be rejected, in favor of allowing

4. *See Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1476 and fn. 16 (Fed. Cir. 1998) (roughly half of all patent appeals decided by the Federal Circuit were wholly or partially reversed, and almost forty percent of claim constructions in a thirty-month period were reversed).

multi-dimensional negotiation and settlements that express contract consideration in multiple currencies. Modern negotiating theory and practice confirm that single variable negotiation will be *less* likely to produce settlement, and less likely to produce maximum settlement value, than if the parties are allowed to trade multiple variables to advance their differently valued interests. *Getting to Yes* at 56; *Duffy*, 233 F.3d at 998.

For any and all of the foregoing reasons, this Court should affirm the ruling of the Eleventh Circuit and the District Court's judgment.

Respectfully submitted,

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AMICUS CURIAE BRIEF

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In the Supreme Court of the United States

FEDERAL TRADE COMMISSION, PETITIONER

v.

ACTAVIS, INC., ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

BRIEF FOR MERCK & CO., INC. AS AMICUS CURIAE SUPPORTING RESPONDENTS

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BRIEF FOR MERCK & CO., INC. AS AMICUS CURIAE SUPPORTING RESPONDENTS

INTEREST OF AMICUS CURIAE

Merck & Co., Inc. (Merck),[1] is a global leader in health care, committed to improving health and well-being around the world. As a leading manufacturer of pharmaceutical products, Merck has a substantial portfolio of patents that protect its inventions. Merck has considerable experience not only with defending its pa-

[1] Pursuant to Rule 37.6, Merck affirms that no counsel for a party authored this brief in whole or in part; no such counsel or a party made a monetary contribution to fund its preparation or submission; and no person other than Merck or its counsel made such a monetary contribution. The parties have consented to the filing of this brief, and copies of their letters of consent are on file with the Clerk's Office.

tents in litigation within the framework of the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), but also with defending settlements of patent litigation in subsequent antitrust litigation.

In particular, Merck and its predecessor Schering-Plough Corporation (Schering) have spent more than a decade defending against antitrust actions brought as a result of Schering's settlements of patent litigation involving the brand-name drug K-Dur 20 (K-Dur). Those actions included an administrative action filed by the Federal Trade Commission (FTC) and a number of subsequent actions filed by private plaintiffs. Remarkably, two federal courts of appeals applied divergent legal standards in considering the legality of those very same settlements. Compare *Schering-Plough Corp.* v. *FTC*, 402 F.3d 1056 (11th Cir. 2005), cert. denied, 548 U.S. 919 (2006), with *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012). Merck has filed a petition for a writ of certiorari from the Third Circuit's decision, which is currently pending before this Court. See *Merck & Co., Inc.* v. *Louisiana Wholesale Drug Co.*, No. 12-245 (filed Aug. 24, 2012).

Merck respectfully submits that the K-Dur litigation serves as a useful case study for this Court to consider in determining the appropriate antitrust standard applicable to settlements of pharmaceutical patent litigation between brand manufacturers and generic manufacturers, where the settlement includes a payment from the brand manufacturer to the generic manufacturer. Specifically, the K-Dur litigation illustrates why the Court should take no comfort in the FTC's assurance that the "quick look" standard it proposes would leave parties in pharmaceutical patent litigation with a range of meaningful settlement options. Under the FTC's standard,

any settlement term other than an agreement to allow the generic manufacturer to enter the market before the expiration of the patent will potentially subject the manufacturers to the kind of multi-year, multi-front antitrust litigation that Merck has endured in the wake of the K-Dur settlements. In practice, therefore, the FTC's "quick look" standard will operate no differently from a per se prohibition on any settlement term other than an early entry date. The end result will be fewer efficient patent settlements and a less competitive and dynamic pharmaceutical industry.

SUMMARY OF ARGUMENT

In its opening brief, the Federal Trade Commission purports to reject a rule of per se condemnation of pharmaceutical patent settlements that involve payments from the brand manufacturer to the generic manufacturer, and to offer as an alternative the so-called "quick look" mode of antitrust analysis. The FTC asserts that, unlike the scope-of-the-patent standard advocated by respondents, the "quick look" standard would prohibit those payments that are truly anticompetitive while, at the same time, leaving parties to pharmaceutical patent litigation with a broader range of meaningful settlement options than would be available under a per se regime. But given how antitrust litigation in this context actually plays out in practice—something Merck is all too qualified to comment upon—there is no meaningful difference between the FTC's proposed standard and per se condemnation of settlements containing payments. Indeed, the FTC's standard would effectively amount to per se condemnation of settlements on *any* terms except an early entry date. This Court should reject the FTC's aggressive and overbroad approach and adopt the scope-of-the-patent standard instead. The

scope-of-the-patent standard is the only standard that is both workable and capable of bringing a measure of certainty to this area of the law.

A. The FTC acknowledges two "primary" exceptions that parties could invoke under its proposed standard to attempt to overcome the presumption that a settlement containing a payment is illegal. The first is when the payment is made in exchange for "bona fide fair consideration," such as a license for intellectual property owned by the generic, or raw materials supplied by it. The second is when the payment is commensurate with the litigation costs avoided by settlement.

B. The FTC conveys the impression that these exceptions would leave parties in pharmaceutical patent litigation with a range of meaningful settlement options. That is unlikely to be the case in practice, however—as Merck's own experience in the K-Dur litigation amply demonstrates. The settlement that became the focus of the K-Dur litigation contained a payment that seemingly fit neatly into the first of the FTC's "primary" exceptions. The FTC nevertheless viewed the settlement as anticompetitive and issued an administrative complaint in an effort to enjoin it. And even after years of litigation in the FTC administrative action—culminating in a court of appeals decision rejecting the FTC's position and upholding findings that the payment at issue was supported by fair consideration—the K-Dur litigation was far from over. Private plaintiffs picked up where the FTC left off, commencing another multi-year round of litigation that continues to this day. And if this Court were to adopt the FTC's proposed standard and deny Merck's currently pending petition for certiorari, the K-Dur litigation would continue, possibly for years to come.

C. Merck's experience with the K-Dur litigation teaches that, if this Court were to adopt the FTC's pro-

posed standard, parties will be deterred from entering into any pharmaceutical patent settlements that contain payments—or, indeed, any terms other than an early entry date. Even when parties structure their settlements to fit within one of the FTC's exceptions, those settlements will remain vulnerable to attack in follow-on antitrust litigation, which (as in Merck's case) could come in two waves: the first initiated by the FTC, and the second by private plaintiffs. By the FTC's own admission, parties to such settlements will ordinarily be unable to terminate follow-on antitrust litigation through motions to dismiss. They will therefore face the prospect of enormous and asymmetric discovery costs—with no guarantee that they will be able to prevail at the summary-judgment stage or beyond.

Moreover, in both private actions and FTC actions, parties inevitably will face the prospect of a "trial within a trial" on the merits of the underlying patent litigation. In addition to increasing the costs and burdens associated with follow-on antitrust litigation, such relitigation of the patent merits would defeat the very point of the settlement. Prudent parties will forgo running those risks and simply avoid entering into settlements that involve payments from the brand manufacturer to the generic manufacturer, even in cases in which the payment would seemingly qualify for one of the FTC's exceptions. And without the ability to use payments as one tool to facilitate settlements, the inevitable result will be fewer settlements of pharmaceutical patent disputes.

D. Finally, the FTC's proposed standard will do more than effectively prohibit settlements that contain actual payments. As the FTC's statements in other forums (if not before this Court) make clear, the FTC appears to take the position that any settlement term except an early entry date is presumptively illegal. The

scope of the FTC's proposed rule is therefore breathtaking. If Congress had intended such a rule in the Hatch-Waxman Act, one might reasonably expect Congress to have said so. It did not do so then, and has not done so since—notwithstanding the FTC's repeated efforts to convince Congress to amend the Act to include a provision prohibiting settlements containing payments. This Court should reject the FTC's request that it adopt a rule that the political branches have thus far rejected. Instead, it should reaffirm that, under established principles of patent and antitrust law, settlements that do not exceed the scope of the patent are ordinarily valid.

ARGUMENT

THIS COURT SHOULD REJECT THE FTC'S PROPOSED 'QUICK LOOK' STANDARD, WHICH IS FUNCTIONALLY EQUIVALENT TO A PER SE PROHIBITION OF A VAST RANGE OF SETTLEMENT TERMS

A. Under The FTC's Proposed Standard, Pharmaceutical Patent Settlements That Contain Payments Are Unlawful, Subject Only To Narrow Exceptions

1. The FTC correctly recognizes that it would be inappropriate to treat pharmaceutical patent settlements that contain payments as "categorically unlawful," on the ground that "per se condemnation would foreclose consideration of possible legitimate justifications for the payment or procompetitive potential that some such agreements may have." Br. 33. The FTC, however, proposes the closest thing to a per se standard: a "quick look" standard, under which a pharmaceutical patent settlement that contains a payment is presumptively unlawful unless the parties to the settlement can demonstrate that "any money that changed hands was for something other than a delay." Br. 37 (quoting *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012)).

The FTC acknowledges two "primary" exceptions that parties can invoke in an effort to overcome the presumption of illegality. The first is when the payment "reflect[s] bona fide fair consideration" for "the generic manufacturer's provision of property or services unrelated to the brand-name manufacturer's monopoly." Br. 37. Such collateral transactions are in fact relatively common. Brand and generic manufacturers interact with each other across a range of different markets; separate and apart from their shared interest in the drug at issue in the patent litigation, they will often have complementary business models and genuine needs for each other's goods and services. When the parties cannot agree on an entry date for the generic version of a brand-name drug, therefore, it will naturally make sense for them to explore ways of bridging their differences that involve collateral transactions. Those transactions may involve a payment by the brand manufacturer to the generic manufacturer "for [intellectual property] licenses, for the supply of raw materials or finished products, [or] for helping to promote products" licensed by the brand manufacturer to the generic. Michael A. Carrier, *Review: A Response to Seven Critics*, 61 Ala. L. Rev. 597, 613 (2010).

The second exception acknowledged by the FTC is when the payment is "commensurate with the litigation costs that the brand-name manufacturer avoided by settling." Br. 38. As with collateral transactions, payments commensurate with litigation costs can help to bridge the gap between the parties on the entry date for the generic version of a brand-name drug, thereby facilitating settlement. As even critics of payments from brand manufacturers to generic manufacturers have recognized, there is nothing objectionable about payments that do not exceed litigation costs, because "the parties would

have been required to spend this money in any event." Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 Mich. L. Rev. 37, 76-77 (2009).

2. By identifying those two categories of payments that would remain permissible under a "quick look" rule, the FTC seeks to create the impression that parties to pharmaceutical patent litigation would be left with a wide range of tools to effectuate settlement. At the same time, however, the FTC makes clear that, even if parties structure their settlements so as to fall squarely within one of the FTC's exceptions, there is no guarantee that the settlements will be upheld. With regard to the exception for collateral transactions, for instance, the FTC takes the position that there is "no fixed formula" for determining whether a settlement qualifies for that exception. Br. 37. Instead, a court reviewing such a settlement "would need to consider the totality of the circumstances surrounding the agreement," taking into account such amorphous and subjective factors as "whether other terms of the side transaction comported with industry standards"; "a history of demonstrated interest in or need for the property or services on the part of the brand-name manufacturer"; and "the course and content of the manufacturers' negotiations over the agreements." Br. 37-38.

And as Merck's own experience in the K-Dur litigation amply demonstrates, practice belies the FTC's promise. If this Court were to adopt the FTC's standard, it is certain that parties seeking to invoke the exceptions to the rule of presumptive illegality will face extreme skepticism from the FTC. And even if the parties are successful in warding off the FTC—either by convincing it not to take action or by defeating any action after it is filed—the parties will likely have to defend

against antitrust actions filed by private plaintiffs. As a practical matter, therefore, it will be too expensive, and carry too many uncertainties, for parties to pharmaceutical patent litigation seriously to consider settling on terms other than an early entry date—with the result that, in many cases, parties will be unable to reach settlement at all.

The FTC's "quick look" standard will therefore function in much the same way as a per se prohibition. It will limit the range of settlements of pharmaceutical patent litigation to precisely one type: settlements consisting solely of an early entry date for the generic drug.

B. The K-Dur Litigation Illustrates Why The FTC's Proposed Standard Will Operate As The Functional Equivalent Of A Per Se Prohibition

The K-Dur litigation provides a vivid example of the protracted ordeal that will await parties under the FTC's proposed standard if they seek to resolve pharmaceutical patent litigation on terms other than an early entry date. The settlement that was the focus of the litigation included a payment that seemingly fit neatly into the FTC's first "primary" exception to the rule of presumptive illegality. As part of its settlement of patent litigation with the generic manufacturer Upsher-Smith Laboratories (Upsher), Schering agreed to pay Upsher $60 million payment for international rights to Upsher's promising cholesterol drug, Niacor-SR.

Schering presented substantial evidence that the payment served its stated purpose and was not a so-called "reverse payment" in disguise. Schering had a documented, preexisting interest in acquiring a sustained-release niacin drug such as Niacor-SR. In order to ensure that the Niacor-SR license was purchased for fair value, Schering had an employee with no knowledge of the patent litigation evaluate the drug's sales poten-

tial—and that employee determined that the value of the license was *four times* what Schering ultimately paid. The FTC nevertheless viewed the Upsher settlement as anticompetitive and issued an administrative complaint in an effort to enjoin it. And even after years of litigation in the administrative action—in which the parties to the settlement prevailed first before an administrative law judge and again before the Eleventh Circuit—the K-Dur litigation was far from over. Private plaintiffs picked up where the FTC left off, commencing another multi-year round of litigation that continues to this day—and that promises to continue into the future if this Court adopts the FTC's proposed standard. The history of the K-Dur litigation warrants tracing in some detail, because it demonstrates why the FTC's promise that some payments will remain permissible is entirely illusory.

1. Schering began developing K-Dur nearly thirty years ago as a treatment for potassium deficiency. In 1989, the Patent and Trademark Office issued a patent for the formulation of K-Dur. FDA subsequently approved Schering's application for K-Dur, and the drug became a commercial success. Pursuant to the Hatch-Waxman Act, Upsher filed an application with FDA for a generic version of K-Dur; in connection with that application, Upsher contended that Schering's patent for K-Dur was invalid and would not be infringed by their generic versions. Schering responded by filing a patent-infringement action against Upsher. See *In re K-Dur Antitrust Litig.*, Civ. No. 01-1652, 2009 WL 508869, at *4, *6-*8 (D.N.J. Feb. 6, 2009).

Upsher and Schering litigated fiercely, with extensive discovery over an eighteen-month period. Just hours before the trial was scheduled to begin, the parties reached a settlement. Under the terms of that settlement, Schering granted Upsher a license to market a

generic version of K-Dur starting on September 1, 2001, some five years before the expiration of the patent. Schering also agreed to pay Upsher $60 million over three years (plus additional amounts contingent on sales) for international rights to Niacor-SR. See *K-Dur*, 2009 WL 508869, at *6-*8.

2. The litigation over the validity of the Upsher settlement began in 2001, when the FTC issued an administrative complaint against Schering and Upsher.[2] The FTC alleged that their settlement constituted an unfair method of competition in violation of Section 5 of the FTC Act, 15 U.S.C. 45. The FTC's theory was that the settlement was invalid because the $60 million royalty payment was designed to "induce [the generic manufacturers] to agree to delay launching generic versions of K-Dur" and thus to "protect[] [Schering] from competition in the relevant markets." Compl. at 9, *In re Schering-Plough Corp.*, F.T.C. Dkt. No. 9297 (Mar. 30, 2001).

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[2] The FTC also sought to enjoin a second K-Dur-related settlement involving ESI-Lederle (ESI), a generic manufacturer that filed its application for approval after Upsher. Under the terms of that settlement, Schering granted ESI a license to market a generic version of K-Dur starting on January 1, 2004. At the urging of the federal magistrate judge who oversaw a court-ordered mediation of the dispute, Schering also agreed to pay $5 million to ESI, which the magistrate described as "nothing more than legal fees," plus an additional sum of up to $10 million contingent upon FDA approval. See *K-Dur*, 2009 WL 508869, at *9-*10. Although the payment to ESI seemingly implicated the second of the FTC's "primary" exceptions (for payments commensurate with litigation costs), and although the FTC itself admitted that there was "relatively limited evidence" that the ESI settlement was anticompetitive, the FTC nevertheless challenged the settlement along with the Upsher settlement. *In re Schering-Plough Corp.*, 136 F.T.C. 956, 1056 (2003). Before trial, the FTC entered into a settlement with American Home Products, ESI's parent. *Id.* at 962.

After the filing of the complaint, the parties engaged in months of intense and costly discovery and proceeded to trial before an administrative law judge (ALJ). The trial lasted nine weeks, with the trial transcript covering some 8,289 pages; the ALJ admitted thousands of exhibits into evidence and heard testimony from 41 fact and expert witnesses.

Rejecting the "emotional appeal" made by the FTC at trial, the ALJ ruled in the manufacturers' favor and dismissed the complaint. *In re Schering-Plough Corp.*, 136 F.T.C. 1092, 1096 (2002). In a detailed, 177-page opinion, the ALJ, applying a rule-of-reason standard, concluded that the FTC had failed to prove that "the challenged agreements had the effect of injuring competition." *Id.* at 1234. Critically for present purposes, the trial focused on whether the collateral transaction involving Niacor-SR was a bona fide, economically rational transaction, or a sham transaction with no meaningful consideration. The FTC's chief expert witness conceded that, if Schering had purchased Niacor-SR for "fair value," it would not raise competitive concerns. *Id.* at 1135.

The ALJ first determined that there was no evidence that, but for the Niacor-SR transaction, the parties would have agreed on an earlier entry date. The earliest entry date to which Schering was willing to agree was September 1, 2001. Upsher was unwilling to agree to a settlement consisting solely of that early entry date, because it was experiencing serious cash-flow problems and needed cash in order to remain competitive in the pharmaceutical market. The ALJ determined that the collateral transaction was necessary in order to bridge the gap between the parties' settlement positions; without that transaction, the ALJ found, the parties would have proceeded to trial. See 136 F.T.C. at 1122-1125, 1134-1135, 1250-1252.

The ALJ then determined that the collateral transaction involving Niacor-SR was a legitimate, fair-value transaction. In so doing, the ALJ made a number of relevant factual findings:

- Schering told Upsher during the negotiations that it was willing to consider a collateral transaction involving Niacor-SR, but that it would need to be an "arm's length" transaction that could "stand on [its] own two feet." 136 F.T.C. at 1124.

- Consistent with Schering's desire to enter into an "arm's length" transaction, Schering assigned the task of valuing the Niacor-SR license to an executive in Schering's global marketing unit, who, according to the ALJ, was "unaware that the Niacor opportunity had any connection to a patent suit." *Id.* at 1126. The executive ultimately concluded that the license would be worth more than $100 million in annual sales, for a total (at net present value) of $225 million to $265 million to Schering—roughly four times what Schering ultimately paid. *Id.* at 1126, 1132-1133, 1160.

- The executive's analysis was consistent with that of an internal Upsher report—prepared before the K-Dur patent litigation commenced—which stated that Niacor-SR was a "highly valued asset" with the potential for annual sales of $100 million to $400 million. *Id.* at 1139.

- Before entering into the settlement with Upsher, Schering had explored a deal with Kos Pharmaceuticals (Kos) for the rights to Niaspan, a sustained-release niacin drug nearly identical to Niacor-SR. The negotiations between Kos and Schering over Niaspan broke down only weeks

before Upsher offered the Niacor-SR license to Schering. A Schering sales forecast projected that annual sales of Niaspan could reach $134 million; an independent Wall Street analyst report estimated that annual sales could exceed $240 million. *Id.* at 1140-1141, 1147.

- The Niacor-SR license was contingent on approval from Schering's board. The board concluded that the transaction was "an agreement that would make sense in and of itself independent of anything else." *Id.* at 1133.

3. Notwithstanding the ALJ's detailed findings, the FTC reversed the ALJ's decision. *In re Schering-Plough Corp.*, 136 F.T.C. 956 (2003). The FTC held that the ALJ had erred by applying the rule-of-reason standard. *Id.* at 966. In the FTC's view, "[a]bsent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for [a] payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise." *Id.* at 988 (footnote omitted).

In invalidating the settlement between Schering and Upsher, the FTC attacked the ALJ's determination that the collateral transaction involving Niacor-SR was a legitimate, fair-value transaction. To begin with, the FTC nitpicked Schering's contemporaneous valuation of the Niacor-SR license: the FTC noted that Schering personnel had hypothesized reasons why the market for niacin-releasing drugs might be smaller than originally thought, and it questioned whether the Schering executive tasked with the valuation analysis (who held an advanced degree in pharmacology) had adequately taken into account concerns about the safety and efficacy of

niacin-releasing drugs. See 136 F.T.C. at 1020-1022, 1151.

The FTC's determination that the collateral transaction involving Niacor-SR was a sham, however, was primarily driven by the "[i]nferences" that it claimed could be drawn from Schering's *post-settlement* conduct. See 136 F.T.C. at 1041. The settlement between Schering and Upsher took place on June 18, 1997. The evidence presented at trial showed that Schering personnel spent much of the summer of 1997 laying the groundwork to begin marketing Niacor-SR in Europe. In November 1997, however, Kos announced the results from the first full quarter of sales for Niaspan. Those results were disappointing—so much so that it caused Kos's share price to plummet to $5 per share, down from a high of $44. Schering understandably decided to put the launch of Niacor-SR "on hold," and ultimately never pursued it. See *id.* at 1163-1164.[3]

Even though there was a rational explanation for Schering's decision to suspend the Niacor-SR launch, the FTC seized upon that decision as evidence that Schering's *pre-settlement* conduct was nothing more than an elaborate ruse, designed to disguise the fact that the payment was being made for the purpose of restraining trade. See 136 F.T.C. at 1051.

4. The Eleventh Circuit vacated the FTC's order. *Schering-Plough Corp.* v. *FTC*, 402 F.3d 1056 (11th Cir.

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[3] As it turned out, Schering's sales projections for the market for sustained-release niacin drugs ultimately proved to be too low, rather than too high. Despite its disappointing launch, Niaspan proved to be a blockbuster drug, with annual sales of $800 million by 2008. In 2008, Abbott Laboratories purchased Kos—which was essentially a one-product company—for over $3 billion. See C.A. App. at 191, 1269, 1281, *K-Dur*, *supra*.

2005). Disagreeing with the FTC on the appropriate legal standard, the court concluded that "the proper analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects." *Id.* at 1066. The court proceeded to determine that the record did not contain substantial evidence to support the conclusion that "the challenged agreements restrict competition beyond the exclusionary effects of [Schering's] patent." *Id.* at 1068.

The Eleventh Circuit did not stop there, however. It proceeded to criticize the FTC's factual determinations—and, in particular, its determinations regarding the Niacor-SR transaction. The court noted the evidence in the trial record that "Schering personnel evaluated Niacor, and forecast its profit stream with a net present value of $225-265 million"—a figure that far exceeded the amount of the royalty payments. See 402 F.3d at 1068-1069. The court also noted the evidence that "Schering had a long-documented and ongoing interest in licensing an extended-release niacin product." *Id.* at 1069. By contrast, the court viewed the evidence on which the FTC had relied in reaching its contrary determination as "forced," "unconvincing," and "meretricious." *Id.* at 1070.

Of note here, the Eleventh Circuit indicated that it was "troubled" by the inferences the FTC drew from Schering's post-settlement conduct. See 402 F.3d at 1069. The court described the expert testimony on which the FTC relied as an "unpersuasive appraisal" of Schering's post-settlement conduct that "blatantly ignored the parties' ongoing communications and the fact that the

niacin market essentially bottomed out" after the settlement was concluded. *Ibid.*[4]

The FTC filed a petition for certiorari. After the United States filed a brief opposing the petition, this Court denied review. 548 U.S. 919 (2006).

5. The Court's order denying certiorari brought the FTC administrative action to a close, some five years after it started. But it was by no means the end of the K-Dur story. Private plaintiffs filed a number of follow-on antitrust actions against Schering and Upsher. The Judicial Panel on Multidistrict Litigation transferred those actions filed in other districts to the District of New Jersey. As matters currently stand, there are three pending private actions, including a certified class action filed by direct purchasers of K-Dur. All of the complaints allege that, by virtue of the payment, Schering's settlement with Upsher constituted an unlawful restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. 1.

Much as in the FTC action, the parties engaged in eighteen months of intensive, costly discovery, involving numerous depositions and the production of millions of pages of documents. At the close of discovery, Schering and Upsher filed motions for summary judgment, which were referred to a special master. "[A]ppl[ying] an analysis consistent with the approach" taken by the Eleventh Circuit in the FTC proceedings, the special master rec-

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[4] A former official in the FTC's Bureau of Competition voiced similar criticism of the FTC's reliance on Schering's post-settlement conduct. As he put it, "[t]he legality of the settlement agreement should be tested by the facts as they appeared when the agreement was made and not by subsequent events." M. Howard Morse, *Settlement of Intellectual Property Disputes in the Pharmaceutical and Medical Device Industries: Antitrust Rules*, 10 Geo. Mason L. Rev. 359, 398 (2002).

ommended that the motions be granted. *K-Dur*, 2009 WL 508869, at *27. He determined that "there is no evidence that any * * * aspects of the settlement exceeded the exclusionary scope of [Schering's] patent." *Ibid.*

The district court adopted the special master's report and recommendation and granted summary judgment to Schering and Upsher. See *In re K-Dur Antitrust Litig.*, Civ. No. 01-1652, 2010 WL 1172995 (D.N.J. Mar. 25, 2010).

6. The Third Circuit reversed in relevant part and remanded, creating a circuit conflict by becoming the first court of appeals to adopt the "quick look" standard. See *K-Dur*, 686 F.3d at 218. The court held that any pharmaceutical patent settlement that includes a payment from the brand manufacturer to the generic manufacturer is presumptively invalid, with the manufacturers bearing the burden of showing that the payment "was for a purpose other than delayed entry" or "offers some pro-competitive benefit." *Ibid.*

The K-Dur litigation therefore persists to this day—some sixteen years after the initial settlement between Schering and Upsher; twelve years after the FTC issued its administrative complaint; and six years after the patent for K-Dur actually expired. And if this Court were to adopt the FTC's proposed standard and deny Merck's petition for certiorari, the K-Dur litigation would continue, possibly for years to come. The district court would presumably conduct another round of briefing on renewed motions for summary judgment, in which Merck and Upsher would argue that they are entitled to invoke the exception for payments that are supported by fair consideration. Any order on those motions would likely be followed by yet another appeal to the Third Circuit. And if Merck and Upsher do not prevail on their mo-

tions, the case would be set for trial—potentially two decades after the settlement at issue was executed.

* * * * *

The moral of the K-Dur story is that, under the FTC's proposed standard, parties to pharmaceutical patent settlements that contain payments will likely face multiple rounds of costly and burdensome antitrust litigation. As we will explain in the next section, that will be true even where, as here, the parties have compelling evidence that the payment at issue falls within one of the FTC's exceptions to its rule of presumptive illegality. Entering into a settlement that subjects the parties to costly and uncertain antitrust litigation in the future defeats the very point of settlement, which is to achieve a complete and final resolution of the controversy at hand. For that reason, most parties will avoid entering into settlements on terms other than an early entry date—with the net result that pharmaceutical patent litigation will be much harder to resolve before trial. In practice, therefore, the FTC's standard will function in the same manner as the per se rule that the FTC purports to forswear—and that this Court has historically been "reluctan[t] to adopt." *State Oil Co.* v. *Khan*, 522 U.S. 3, 10 (1997).

C. Faced With The Prospect Of Protracted Litigation Like The K-Dur Litigation, Parties To Pharmaceutical Patent Settlements Will Avoid Entering Into Settlements That Involve Payments

Should this Court adopt the FTC's proposed standard, parties will be deterred from entering into pharmaceutical patent settlements that contain payments—or, indeed, any terms other than an early entry date. The practical consequence of such a standard will be to ren-

der it impossible to reach settlements in a substantial amount of pharmaceutical patent litigation.

1. To begin with, parties that enter into settlements containing payments will have to reckon with the FTC—which, as the K-Dur litigation demonstrates, has historically taken a dim view of such settlements, even in the face of overwhelming evidence that the payment is not anticompetitive. Particularly in light of the FTC's amorphous, totality-of-the-circumstances test for determining whether an exception to the rule of presumptive illegality has been satisfied, parties will never have any confidence that a settlement containing a payment will be acceptable to the FTC. And as the K-Dur litigation amply illustrates, if the FTC ultimately seeks to enjoin the settlement, the ensuing litigation burden will be substantial, even where the parties have compelling evidence that their settlement involves one of the categories of payments that would purportedly remain permissible under a "quick look" rule. See pp. 11-17, *supra*.

2. Whether or not the FTC takes action, parties that enter into settlements containing payments will face the prospect of antitrust actions filed by private plaintiffs. Notably, the FTC seemingly takes the position that, under its proposed "quick look" standard, the mere allegation that a pharmaceutical patent settlement contains a payment from the brand manufacturer to the generic manufacturer will be sufficient for a complaint to survive a motion to dismiss. See Br. 55-56. Such an allegation is all that would be needed to establish the presumptive illegality of the settlement—and therefore that the plaintiffs' allegation that the defendants unlawfully restrained trade is a "plausible" one. See *Bell Atlantic Corp.* v. *Twombly*, 550 U.S. 544, 565-566 (2007); cf. Mark Anderson & Max Huffman, *'Iqbal,' 'Twombly,' and the Expected Cost of False Positive Error*, 20 Cornell J.L. &

Pub. Pol'y 1, 38 (2010) (contending that, under the "quick look" standard, "the plaintiff's initial burden * * * is merely to demonstrate the existence of a suspect agreement").

The "naked assertion[]" that a settlement contains a payment would therefore be sufficient to "unlock the doors of discovery." *Ashcroft* v. *Iqbal*, 556 U.S. 662, 678-679 (2009) (citation omitted). And the prospect of discovery is a particularly frightening one for defendants in private antitrust actions, where the costs of discovery are enormous and asymmetric.

This Court has previously noted the "unusually high cost of discovery in antitrust cases." *Twombly*, 550 U.S. at 558. That is because antitrust actions typically involve "voluminous documentary and testimonial evidence, extensive discovery, complicated legal, factual, and technical (particularly economic) questions, numerous parties and attorneys, and substantial sums of money." *Manual for Complex Litigation* § 30, at 519 (4th ed. 2004). Those burdens are only magnified where, as here, the court has certified a class of plaintiffs; one court has described antitrust class actions as "arguably the most complex action[s]" to litigate. *In re Linerboard Antitrust Litig.*, 296 F. Supp. 2d 568, 577 (E.D. Pa. 2003) (citation omitted). In such a case, the defendants can reasonably expect to be forced to defend scores of depositions of their personnel and to produce millions of pages of documents, whereas the named plaintiffs would need to do little more than to establish that they purchased the drug in question.

Because of the enormous and asymmetric costs of discovery in antitrust actions, parties contemplating settlements that contain payments will know that, if they enter into those settlements, they will likely have to make additional payments—to antitrust plaintiffs and

their lawyers. In the antitrust context, this Court has recognized that "the threat of discovery expense will push cost-conscious defendants to settle even anemic cases before reaching" the summary-judgment or trial stage. *Twombly*, 550 U.S. at 559. In the face of such enormous and asymmetric costs—to say nothing of the prospect of treble damages—most defendants will succumb to what Judge Friendly aptly termed "blackmail settlements." Henry J. Friendly, *Federal Jurisdiction: A General View* 120 (1973). And the irony of the FTC's approach is that fear of the costs of subsequent *antitrust* litigation will prevent parties from entering into efficient settlements of *patent* litigation, thus generating unnecessary litigation costs that will be passed on to consumers of brand and generic drugs alike.

3. Even if they are willing to endure the burdens of discovery, parties that enter into settlements containing payments will face uncertain prospects at the summary-judgment stage and beyond. For starters, given that "quick look" analysis places the burden on the *defendant* to establish that the conduct in question was procompetitive, a defendant's chances of prevailing at the summary judgment stage will be inherently more uncertain under the FTC's rule than in a typical antitrust case. To be sure, there will be some cases like the K-Dur litigation, in which the parties will be armed with compelling evidence to satisfy that burden. But in many other cases, it will be difficult for the parties to assess whether they will be able to prevail under the FTC's amorphous, totality-of-the-circumstances test for determining whether one of the exceptions has been satisfied. That is particularly true to the extent that the FTC's test ultimately requires an inquiry into the parties' intent at the time they entered into the settlement. See, *e.g.*, Br. 37 (suggesting that the relevant inquiry is whether "any

money that changed hands was *for* something other than a delay") (emphasis added; citation omitted).

At a minimum, the FTC's test would require an *ex post* analysis of whether the consideration provided in a collateral transaction was "fair," or whether the amount of a particular payment was "commensurate" with litigation costs. Br. 37, 38. The FTC itself has previously recognized that such *ex post* analysis "places parties contemplating settlement in the predicament of not knowing, at the time of settlement, whether particular settlement terms will appear unreasonable to a future antitrust tribunal." Pet. Supp. Br. at 4, *FTC* v. *Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273). And that uncertainty is only exacerbated by the fact that the *ex post* analysis will occur years, if not decades, after the settlement is reached. With regard to a collateral transaction, the value of the transaction may look very different in hindsight than it did at the time it was executed. If a brand manufacturer obtains a license from a generic manufacturer but the drug turns out to be unsuccessful, or the brand decides not to pursue it due to unforeseen changes in the market or the emergence of superior business opportunities, the parties to the settlement will run the risk that bad business judgment will be confused with an unlawful restraint of trade. See M. Howard Morse, *Settlement of Intellectual Property Disputes in the Pharmaceutical and Medical Device Industries: Antitrust Rules*, 10 Geo. Mason L. Rev. 359, 398-399 (2002). Yet that is precisely what happened when the FTC sought to invalidate the settlement between Schering and Upsher based on Schering's subsequent decision to suspend the Niacor-SR launch. See pp. 14-15, *supra*.

4. One further point bears emphasis. The FTC concedes that any antitrust standard that would force the parties to litigate the merits of the underlying patent

dispute would be highly problematic. See Br. 54-55. As the court of appeals in this case noted, "deciding a patent case within an antitrust case about the settlement of the patent case" is an "[un]palatable" "turducken task." Pet. App. 36a. Inquiry into the patent merits "defeat[s] the point of settlement," Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, 91 Tex. L. Rev. 283, 288 (2012), because it ensures that the parties simply "trad[e] the uncertainty of the outcome of the patent litigation, based on the patent merits, for the uncertainty of the outcome of the antitrust litigation, based again on the patent merits," Alden F. Abbott & Suzanne T. Michel, *The Right Balance of Competition Policy and Intellectual Property Law: A Perspective on Settlements of Pharmaceutical Patent Litigation*, 46 IDEA 1, 33-34 (2005).

Although the FTC acknowledges the problems with litigating the merits of the underlying patent action in a subsequent antitrust action, the FTC suggests in a footnote that "[q]uantification of damages in a private antitrust action might require an assessment of what sequence of events would likely have ensured in the absence of [the] payment." Br. 55 n.11. Notably, so too do the plaintiffs in the K-Dur litigation, in an amicus brief filed in this case. See Louisiana Wholesale Drug Co. Br. 33 (noting that "nothing would prohibit plaintiffs in an appropriate case from offering evidence of the outcome of the patent litigation but for the * * * payment").

It is far from clear exactly how a court would go about assessing the merits of the underlying patent litigation in a subsequent antitrust action; after all, by virtue of the settlement, the patent merits were never litigated to conclusion, and may not have been litigated extensively. What is clear, however, is that any consideration of the patent merits will inevitably add still more

complexity to the antitrust action. See Pet. 31 (noting that, in the briefing below in the K-Dur litigation, the parties had "addressed at length complex matters of chemistry and patent doctrine" relevant to the generic manufacturers' defense of noninfringement). And to the extent the patent merits are relevant at trial, it will permit plaintiffs to seek discovery relevant to the patent merits from defendants, thus exacerbating the asymmetric burdens of the discovery process. See pp. 21-22, *supra*. Resolving patent issues in this context will be all the more complicated because of the length of time that likely will have passed between the filing of the patent application and the commencement of the antitrust litigation.

Curiously, at the same time the FTC suggests that the patent merits may be relevant at the damages stage of a subsequent antitrust action, it takes the position that they are irrelevant at the liability stage. See Br. 53-54. But it is difficult to see why. Under the "quick look" standard of antitrust review—at least as it is ordinarily understood—the defendant may rebut the presumption that conduct of a particular type is anticompetitive by offering evidence "suggesting that the challenged restraint is 'justified' in that it * * * in fact increases output or reduces price." 11 Herbert Hovenkamp, *Antitrust Law* ¶ 1991, at 335-336 (3d ed. 2011). Indeed, it is the ability to do so that differentiates the "quick look" standard from a standard of per se condemnation. And the most direct way for a brand defendant to demonstrate that there will be no adverse effects on competition from a settlement containing a payment will be to show that it would have prevailed in the underlying patent litigation. See, *e.g.*, Gregory Dolin, *Reverse Payments as Patent Invalidity Signals*, 24 Harv. J.L. & Tech. 281, 284 (2011). By attempting to disable defend-

ants from making such a showing at the liability stage, the FTC makes clear that its "quick look" standard is a per se standard in all but name.

In sum, given the many risks of defending pharmaceutical patent settlements that contain payments from brand manufacturers to generic manufacturers, prudent parties will forgo running those risks and avoid including payments in settlements going forward. As a practical matter, therefore, the FTC's proposed standard will effectively take the option of including payments in settlements off the table.

D. The FTC's Proposed Standard Will Effectively Prohibit Not Only Payments, But Also A Vast Range Of Other Settlement Terms

Finally, the FTC's proposed standard will do more than effectively prohibit settlements that contain actual payments. It will similarly affect a broad array of other settlement terms, leaving only one type of settlement that can unambiguously pass antitrust muster: a settlement consisting solely of an early entry date for the generic drug.

1. In its brief before this Court, the FTC is coy about what, in its view, constitutes a "payment" triggering the rule that "reverse-payment agreements" are "presumptively unlawful." See, *e.g.*, Br. 19. The FTC has been more forthright, however, in other forums. In a recent amicus brief filed in district-court litigation shortly after the Third Circuit's decision in the K-Dur litigation, the FTC took the position that its "quick look" standard should apply not only to settlements that contain *actual* payments from the brand manufacturer to the generic manufacturer, but also to settlements that contain any term that "[f]unctions as a [p]ayment." See FTC Br. at 5, *In re Effexor XR Antitrust Litig.*, Civ. No. 11-5479 (D.N.J.) (filed Aug. 10, 2012). In the settlement

at issue in that case, no payment changed hands; the brand manufacturer simply agreed that it would not launch an authorized generic version of the drug during the generic manufacturer's 180-day period of exclusivity, thereby allowing the generic manufacturer to take advantage of the exclusivity period it already possessed as the first filer under the Hatch-Waxman Act. The FTC nevertheless took the position that the brand manufacturer's agreement not to launch its authorized generic version during that exclusivity period was the functional equivalent of a payment from the brand manufacturer to the generic manufacturer. See FTC Br. at 5-11, *Effexor*, *supra*.

Similarly, in a recent review of pharmaceutical patent settlements, the FTC took the position that royalty payments made *from* a generic manufacturer *to* a brand manufacturer could trigger the rule of presumptive illegality, where the settlement at issue provided that the royalties would be eliminated or reduced upon the brand manufacturer's launch of an authorized generic version. See FTC, *Agreements Filed With the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in Fiscal Year 2010: A Report by the Bureau of Competition* 1 (May 2011). The FTC has therefore taken the position that its rule purportedly concerning "reverse payments" applies in cases involving payments from brand manufacturers to generic manufacturers; payments from generic manufacturers to brand manufacturers; and no payments at all.

In order to understand the breadth of the FTC's position, one has to read between the lines of the FTC's brief. At one point, the FTC states that "[t]he extraordinary and distinguishing feature of reverse-payment agreements * * * is that the defendant generic manu-

facturers receive something * * * that they could not hope to obtain even if they *prevailed* in the litigation." Br. 30. The sole remedy that a generic manufacturer obtains if it prevails in patent litigation under the Hatch-Waxman Act, however, is the ability to enter the market earlier: *i.e.*, upon FDA approval (and expiration of any applicable exclusivity period), rather than upon the subsequent expiration of the patent. The inevitable implication of that statement, therefore, is that any settlement term except an early entry date is presumptively illegal.[5]

If that is really the FTC's position, it should at least have the courage of its convictions and explicitly say so, without forcing readers to take out their decoder rings. But it is perhaps not surprising that the FTC does not wish to expose the breathtaking scope of its proposed rule. Citing not a statutory provision but a law-review

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[5] The breadth of the FTC's position is pernicious for an additional reason. If all that is required to trigger the rule of presumptive illegality is that the generic manufacturer "receive something," it would have the effect of shifting the burden to the defendants even as to cases in which no *net* consideration passes from the brand manufacturer to the generic manufacturer—*e.g.*, cases in which the generic manufacturer receives a payment, but the brand manufacturer receives fair consideration in return. The government has long recognized that settlements of that type are procompetitive. See, *e.g.*, U.S. Br. at 9, *Andrx Pharm., Inc.* v. *Kroger Co.*, 543 U.S. 939 (2004) (No. 03-779). In the event this Court were to adopt some version of the "quick look" standard, it should make clear, at a minimum, that the rule of presumptive illegality is triggered only where the generic manufacturer receives net consideration—and that the plaintiff bears the burden of proving that the rule has in fact been triggered. See, *e.g.*, *United States* v. *Arnold Schwinn & Co.*, 388 U.S. 365, 374 n.5 (1967). In many cases, plaintiffs will be unable to meet that burden. Cf. *Schering-Plough*, 402 F.3d at 1071 (determining that "[t]here is nothing to refute" the proposition that Schering paid a "fair price" for the rights to Niacor-SR).

article (which, in turn, cites nothing at all), the FTC contends that the Hatch-Waxman Act "reflect[s] a strong congressional policy that favors testing the scope and validity of pharmaceutical patents, with a view to realizing the benefits of generic competition at the earliest appropriate time." Br. 30-31 (citing C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1614 (2006)). It is certainly true that the Hatch-Waxman Act provides a mechanism for the litigation of patent disputes before a generic manufacturer brings its product to market. See 21 U.S.C. 355(j)(5)(B)(iii); 35 U.S.C. 271(e)(2)(A). But that is as far as the Hatch-Waxman Act actually goes. Notably absent from the Hatch-Waxman Act is any provision that makes it presumptively illegal to enter into *settlements* of such litigation unless the settlements are based solely on an early entry date.

It is for that reason that the FTC has repeatedly, and unsuccessfully, asked Congress to amend the Hatch-Waxman Act to include a provision prohibiting settlements containing payments from brand manufacturers to generic manufacturers. See, *e.g.*, FTC, *Prepared Statement Before the Sen. Special Comm. on Aging on Barriers to Generic Entry* 20 (July 20, 2006) <tinyurl.com/ftcbarriers>. Now it asks this Court to adopt, by judicial fiat, a rule that is at least as broad as, if not broader than, the rule the political branches have refused to adopt—a rule that would effectively prohibit pharmaceutical patent settlements on any terms except early entry, and thereby render it impossible to reach settlements in a substantial amount of pharmaceutical patent litigation. This Court should reject the FTC's aggressive and overbroad approach to pharmaceutical patent settlements. Instead, it should reaffirm that settle-

ments that do not expand the scope of the patent are ordinarily valid under established principles of patent and antitrust law.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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AMICUS CURIAE BRIEF

SUPREME COURT, U.S.
FILED
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No. 12-416

IN THE

Supreme Court of the United States

FEDERAL TRADE COMMISSION,

Petitioner,

v.

ACTAVIS, INC., ET AL.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF *AMICUS CURIAE* OF NATIONAL ASSOCIATION OF MANUFACTURERS IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

Whether reverse-payment agreements are per se lawful unless the underlying patent litigation was a sham or the patent was obtained by fraud, or instead are presumptively anticompetitive and unlawful.*

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* This is the Question as formulated by Petitioner. Respondents have each proposed slightly different versions of the Question.

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548 U.S. 919 (2006) (No. 05-273)
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INTEREST OF *AMICUS CURIAE*[1]

The National Association of Manufacturers ("NAM") is the nation's largest industrial trade association, representing small and large manufacturers in every industrial sector and in all 50 states. The NAM's mission is to enhance the competitiveness of manufacturers by shaping a legislative and regulatory environment conducive to economic growth in the United States and to increase understanding among policymakers, the media and the general public about the vital role of manufacturing to America's economic future and living standards.

Many of its members hold patents, trademarks or copyrights, and consider intellectual property to be important assets, and many of them will be affected by the decision in this case.

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[1] Pursuant to Rule 37.2(a), all parties have consented to the filing of this brief. Copies of those consents have been lodged with the Clerk.

Pursuant to Rule 37.6, *amicus* affirms that no counsel for any party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae* nor its counsel made a monetary contribution to the preparation or submission of this brief.

PRELIMINARY STATEMENT AND SUMMARY OF ARGUMENT[2]

This case arises from settlements of patent litigation brought under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act). The settlements in this case involve Abbreviated New Drug Applications (ANDAs) governed by the Hatch-Waxman Act before it was amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), and thus are known in the industry as "pre-MMA" settlements.

As is not uncommon, the patent owner, Solvay Pharmaceuticals' predecessor, sued the generic manufacturers [both of whom had filed "Abbreviated New Drug Applications" for a generic equivalent)]. That litigation went through discovery and some motion practice in the Northern District of Georgia, and was then settled after partially dispositive motions were filed, but before they were decided. The FTC does not claim that the underlying patent litigation was a sham, nor does the agreement at issue give Solvay a monopoly for a period beyond that granted by its patents.

The settlement of the patent litigation "split the baby." The generic manufacturers agreed not to

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[2] *Amicus* adopts the Statement of Respondent Actavis, Inc.

market their product for a period equal to approximately one-half of the remaining period of patent protection, and Solvay agreed to pay Watson and Paddock fees for "marketing assistance" for the brand-name AndroGel product during the remaining patent-protected period and to provide "back up production capacity."

The FTC asserts that the settlement is an anticompetitive agreement because it involves a payment to the generic manufacturers to stay out of the market for a time, giving the patent holder a monopoly for a period of time, notwithstanding the fact that the agreed period of generic abstention was shorter than the monopoly period inherent in the patent.

The district court dismissed the FTC's lawsuit and the Eleventh Circuit, agreeing with precedent in the Second and Federal Circuits (*In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005), *amended*, 466 F.3d 187 (2d Cir. 2006), *cert. denied*, 551 U.S. 1144 (2007); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) ("*Cipro*")), affirmed the district court's dismissal of the FTC's complaint because the underlying patent litigation was not a sham, and because the non-compete term was no greater than the period during which Solvay would have had exclusivity had its patent been upheld.

The central question is whether a settlement of *bona fide*, non-sham, patent litigation unlawfully restrains trade, where the patent was not procured

by fraud and the settlement terms do not exceed the scope of the patent's exclusionary period. Critical to this inquiry is the existence of the patent, which is presumed to be valid and grants its holder the right to exclude competition within the patent's scope.

The FTC asks this Court to hold that "reverse-payment" patent settlements are presumptively unlawful. The FTC contends that a rule of presumptive unlawfulness "serves the purposes of competition law, patent law, and the Hatch-Waxman Amendments." FTC-Br.19-40.

The test proposed by the FTC omits any consideration of the inherent right to exclude emanating from the patent, which, by its nature, is a grant by the government to the patentee of a legal monopoly for a period of time.

The FTC's "Questions Presented" and the arguments it makes, moreover, are not limited to the Hatch-Waxman Amendments or to the pharmaceutical industry and have immense implications. This Court's answer to the question as posed by the FTC will affect all patentees, and will affect broad and vital sectors of the United States' economy.

If the FTC's rule were adopted, it would put patent holders at risk whenever they settle an infringement action – which is frequently an expensive "crap shoot" – by licensing the patent in exchange for a significant license fee or by entering

into a "reverse payment" arrangement. A decision in favor of the FTC could well discourage companies from undertaking lengthy and expensive research and development programs, the cost of which can be recouped only through a significant period of patent monopoly protection.

The FTC's proposed rule would throw the long-established intellectual property (patent, trademark, copyright) ("IP") regimes into turmoil; it would upset the reasonable economic expectations of broad swaths of industry in the United States grounded in decades of patent and antitrust law. It would likely do immeasurable damage to the domestic economy and the United States' competitiveness in the world economy.

The decision and judgment of the Court of Appeals for the Eleventh Circuit should be affirmed because that court's decision and reasoning are consistent with this Court's precedents, the purposes of the Patent Act, and the Sherman Act, 15 U.S.C. § 1.

ARGUMENT

I.

THE FTC'S PROPOSED RULE WILL HAVE AN IMMENSE IMPACT ON THE ECONOMY

The impact of the FTC's proposed rule on the economy is difficult to exaggerate. This Court's resolution of this case will have a broad impact on innovators and patent holders in the manufacturing sector. Although the focus of this case is the pharmaceutical industry, the rule proposed by the FTC is not limited to that industry, and would apply to all intellectual property, and all industrial sectors that are intellectual property-intensive.

Inventions, embodied in patents, are a major driver of long-term regional economic performance. *See*, Jonathan Rothwell, José Lobo, Deborah Strumsky, and Mark Muro, Patenting Prosperity: Invention and Economic Performance in the United States and its Metropolitan Areas (Brookings Institution, February 2013), available at http://www. brookings.edu/research/reports/2013/02/patenting-prosperity-rothwell (last accessed Feb. 26, 2013).

Intellectual property ("IP") intensive industries accounted for about $5.06 trillion in value added[3]:

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[3] "Value added" is the difference between an (continued...)

34.8 percent of total U.S. gross domestic product (GDP), in 2010.

IP-intensive industries accounted for 18.8 percent of all jobs in the economy in 2010. *See* Economic and Statistics Administration and U. S. Patent and Trademark Office. Intellectual Property and the U.S. Economy: Industries in Focus 45 (2012). available at http://www.uspto.gov/news/publications/IP_Report_March_2012.pdf (last accessed Feb. 25, 2013) ("IP and U.S. Economy").

The 75 industries classified as IP-intensive (out of a total of 313 industries categorized) accounted for 27.1 million American jobs, or 18.8 percent of all employment in the economy. in 2010; IP-intensive industries. while direct and indirect activities account for 27.7 percent of all jobs in the economy. Patent-intensive industries, while employing fewer persons than trademark- or copyright-intensive industries. supported a larger multiple of outside supply chain employment. Jobs in IP-intensive industries also pay significantly

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[3](...continued)
industry's total output (sales plus change in inventories arising from production) and the value of its intermediate purchases from other industries (that is. from its supply chain).

better than other jobs.[4] IP and U.S. Economy at 43-44.

United States IP-intensive industries have a significant beneficial impact on the U.S. international trade. Merchandise exports of U.S. IP-intensive industries totaled $775 billion in 2010, accounting for 60.7 percent of total U.S. merchandise exports. Manufacturing industries were responsible for almost 99 percent of IP-intensive merchandise exports in 2010, with pharmaceuticals and medicine accounting for $49.4 billion and medical equipment and supplies accounting for $26.2 billion. From 2000 to 2010, exports of IP-intensive industries increased 52.6%. IP and U.S. Economy at 53.

In the first decade of the twenty-first century, U.S. businesses invested as much in "idea-related intangibles" (approximately $1 trillion) as they did in plant, equipment and other tangible forms of investment. The development of new information technology ("IT") accounted for 28 percent of productivity gains. Capital investment in IT

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[4] Average weekly wages for IP-intensive industries were $1,156 in 2010, 42 percent higher than the $815 average weekly wages in non-IP-intensive private industries. The difference is even greater for workers in patent-intensive industries, who earned $1,407 per week on average. The comparatively high wages in IP-intensive industries correspond to, on average, the completion of more years of schooling by these workers. IP and the U.S. Economy at 50-51.

accounted for 34 percent of productivity gains: and research and development ("R&D") accounted for 10 percent of productivity gains. *See* Carol Corrado, Charles Hulten, Daniel Sichel, "Measuring Capital and Technology: An Expanded Framework," Federal Reserve Board. Finance and Economics Discussion Series. No. 2004-65. August 2004, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=877453 (last accessed Feb. 26, 2013); *see also* Robert J. Shapiro. The Role of Innovation and Intellectual Property in Economic Competition (American Enterprise Institute 2011), available at http://www.aei.org/files/2011/09/29/Innovatio_and_Intellectual_Property_Shapiro.pdf (last accessed Feb. 25. 2013).

From 2000 to 2007, IP-intensive industries spent almost 13 times more on R&D per employee than non-IP-intensive industries ($27,839 versus $2,164 per employee per year) and workers in IP-intensive industries generated approximately double the output and sales per employee than workers in non-IP-based industries: annual output (as measured by value-added) was $218,373 per employee in IP-intensive industries and only $115,239 in non-IP-intensive industries); annual sales averaged $485,678 per employee in IP-intensive industries versus $235,438 per employee in non-IP-intensive industries. *See* Nam D. Pham, The Impact of Innovation and the Role of Intellectual Property Rights on U.S. Productivity. Competitiveness. Jobs. Wages, and Exports (2010).

available at http://www.theglobalipcenter.com/sites/default/files/reports/documents/NDP_IP_Jobs_Study_Hi_Res.pdf (last accessed Feb. 25, 2013).

IP-intensive industries made up nearly half of output and sales of all U.S. industries engaged in international trade and employed more than 30 percent of American workers in those industries. IP-intensive industries accounted for approximately 60 percent of total U.S. exports and in the period 2000-2007, and the annual value of exports per employee in IP-intensive industries was 3.4 times (235 percent) higher than in non-IP-intensive industries ($91,607 versus $27,369). In the period 2000-2007, the annual salaries of workers in IP-intensive industries were, on average, 60 percent higher than the salaries of workers in non-IP-intensive industries ($59,041 versus $37,202/employee/year, respectively). Pham, *id.*

II.

PATENT HOLDERS' RIGHTS

A. Patents Create Legal Monopolies.

The Constitution gives Congress the authority "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8. This language, made explicit in the Patent Act, 35 U.S.C. § 154(a)(1) grants patent holders the

right to exclude others from using or selling the patented invention. *Dawson Chem. v. Rohm & Haas*, 448 U.S. 176, 215 (1980) ("[T]he essence of a patent grant is the right to exclude others from profiting by the patented invention."); *Microsoft Corp. v. i4i P'ship*, 131 S. Ct. 2238, 2242 (2011) ("[A] patent grants certain exclusive rights to its holder, including the exclusive right to use the invention during the patent's duration.").

A patent is, simply put, a legal monopoly:

> The very object of [the patent] laws is monopoly, and the rule is, with few exceptions, that any conditions which are not in their very nature illegal with regard to this kind of property, imposed by the patentee and agreed to by the licensee for the right to manufacture or use or sell the article, will be upheld by the courts.

Bement & Sons v. Nat'l Harrow Co., 186 U.S. 70, 91 (1902).[5]

Patentees can engage in restraints of trade and exclusionary conduct that would violate the antitrust laws absent patent protection: "The patent laws which give a 17-year monopoly on

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[5] Ignoring the constitutional and statutory condonation of patent monopolies, the FTC falsely analogizes licensing or cross-licensing to agreements by competitors to divide markets where no patents are involved, which is *per se* illegal

'making, using, or selling the invention' are *in pari materia* with the antitrust laws and modify them *pro tanto*." *Simpson v. Union Oil*, 377 U.S. 13, 24 (1964). "[P]atent grants [are] an exception" to antitrust restrictions. *United States v. Line Material Co.*, 333 U.S. 287, 309 (1948) unless the patent was improperly acquired (for fraud on the PTO) or improperly asserted (sham litigation). *See Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 178 (1965); *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 51 (1993).[6] "The [patent] monopoly is a property right." *Festo v. Shoketsu Co.*, 535 U.S. 722, 730 (2002); *see DOJ/FTC Guidelines* §1.0 (patent laws "establish[] enforceable property rights for the creators of new and useful products").

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[6] A patentee may, of course, lose antitrust immunity by demanding royalties beyond the patent term, *see Brulotte v. Thys Co.*, 379 U.S. 29, 33 (1964), by using its patent to control the sale of unpatented products, *see Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 491 (1942), or by restricting the resale of patented products, *see United States v. Masonite Corp.*, 316 U.S. 265, 310-11 (1942). "Patent pools," by which multiple patent holders jointly restrain trade beyond what a single patentee could achieve may also not have antitrust immunity. *See Line Material*, 333 U.S. at 288-89; *United States v. New Wrinkle, Inc.*, 342 U.S. 371, 376-79 (1952).

The FTC's proposed rule wipes out over a century of patent-antitrust law.

B. The FTC's Proposed Rule Ignores the Essential Characteristics of Patents.

The "most material fact" in an appropriate antitrust analysis of patent-related agreements "is [that] the agreements concern articles protected by letters patent." *Bement*, *supra* at 88). It is essential in an antitrust analysis of patent-based transaction to acknowledge the patent holder's lawful exclusionary rights. *Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko*, 540 U.S. 398, 411 (2004). The FTC's rule fails completely to do this.

The crux of the FTC's purported patent-law justification for its proposed rule is that patents confer merely "probabilistic" rights and, because the FTC suspects many "weak" patents exist and therefore patent settlements require judicial appraisal beyond the scope-of-the-patent. FTC Br. 44. These arguments are also unsound, because they ignore the presumption of validity attaching to patents. *see* 35 U.S.C. § 282(a) and *United States v. Masonite Corp.*, 316 U.S. 265, 280 (1942), and would usurp the functions of the agency charged with administering the patent system.

The FTC's disregard of the patentee's exclusive rights, unless and until the validity of the patent is established through a judgment after litigation, creates an unworkable and pernicious rule at odds

with precedent.[7] The FTC concedes that basing antitrust analysis on a *prediction* of which side would have prevailed would be "doctrinally anomalous and likely unworkable in practice." FTC Br. 53.

C. The Scope of the patent Rule.

Under the Court's precedents, which the FTC's rule would in effect overrule, the "scope of the patent" rule, a rule which creates predictable guidelines within which the patent holder may operate without facing the threat of antitrust liability. *See United States v. Gen. Elec. Co.*, 272 U.S. 476, 485, 489 (1926) ("[I]t is only when. . . [the patentee] steps out of the scope of his patent rights" that he comes within the operation of the Sherman Act); *United States v. Line Material*, 333 U.S. 287, 300 (1948) ("[T]he precise terms of the grant define the limits of a patentee's monopoly and the area in which the patentee is freed from competition of price, service, quality or otherwise" but "[i]f the limitations in a license reach beyond the scope of the statutory patent rights, then they must be tested by the terms of the Sherman Act").

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[7] In one of many paradoxes in the FTC's litigation position in this case, it concedes, FTC-Br.26-27, "Where there are legitimately conflicting claims, or threatened interferences, a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act," citing *Standard Oil (Indiana) v. United States*, 283 U.S. 163, 171 (1931).

To determine whether a patentee engaged in conduct beyond the protection of its temporary monopoly and is, therefore, potentially in violation of the antitrust laws, one begins by examining whether the restraint exceeds the scope-of-the-patent. *See, e.g., Gen. Talking Pictures v. Western Electric*, 305 U.S. 124, 127 (1938) ("[T]he patentee may grant a license upon any condition the performance of which is reasonably within the reward which the patentee by the grant of the patent is entitled to secure."); *Line Material*, 333 U.S. at 353 ("If the limitations in a license reach beyond the scope of the statutory patent rights, then they must be tested by the terms of the Sherman Act."); *Cipro*, 544 F.3d at 1336 ("[T]he outcome is the same whether the court begins its analysis under antitrust law by applying a rule of reason approach to evaluate the anti-competitive effects, or under patent law by analyzing the right to exclude afforded by the patent.").[8]

D. Patent Litigation Settlements.

This Court has long recognized that settlement of patent litigation, without more, does not violate the antitrust laws. *Standard Oil Co. (Ind.) v. United States*, 283 U.S. 163, 171 (1931) ("Where there are legitimately conflicting claims or

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[8] The "scope of the patent" test harmonizes patent and antitrust law, while the FTC's rule creates an unavoidable and irreconcilable tension between the two legal regimes.

threatened interferences, a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act.").

The FTC nevertheless urges the Court to adopt an antitrust analysis for patent litigation settlements that disregards the patent, in effect treating the patent as though it were nugatory.[9]

The FTC's proposed rule in this case is at odds with "[T]he public policy favoring settlements, and the *statutory right of patentees to exclude competition within the scope of their patents*, would potentially be frustrated by a rule of law that subjected patent settlements involving reverse payments to automatic or near-automatic invalidation." U.S. Br. 10-11 (emphasis added) in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1073 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006) (filed May 17, 2006), 2006 WL 1358441 at *12. As the FTC now concedes, the government's position in *Schering-Plough* is irreconcilable with its position here ("In those [earlier] briefs], the United States did not endorse the FTC's view that

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[9] The FTC takes the position that the patent has *no* scope until courts have established its validity and coverage in litigation. *See* FTC Br. 25-26 ("simply holding a patent does not result in the automatic exclusion of potential rivals;" and *id.* at 40 ("[t]o enforce a contested patent, a patentee must prove that the accused product or process falls within the scope of the patent's claims as properly construed.")

reverse-payment settlements are presumptively anticompetitive." FTC Br.41 n.9.

The FTC concedes that *Standard Oil* establishes the general rule that patent settlements do not violate the antitrust laws. FTC Br.26-27. *Standard Oil* teaches that (1) parties may settle patent litigation without antitrust liability as long as there were "legitimately conflicting claims," 283 U.S. at 171; (2) such conflict turns on the nominal scope-of-the-patent, which is not to be second-guessed by inquiring whether infringement would have been proven, *id.* at 181[10]; and (3) the financial terms and consideration of a settlement are irrelevant, *id.* at 171-172.

The Court in *Standard Oil* noted the frequent necessity of exchanging financial consideration in reaching settlements: "An interchange of patent rights and a division of royalties according to the value attributed by the parties to their respective patent claims is frequently necessary if technical advancement is not to be blocked by threatened litigation." *Id.*[11]

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[10] Because the patents are presumptively valid, and there was no allegation of bad-faith in its acquisition, the Court did "not consider any of the issues concerning the validity or scope of the . . . patents."

[11] The Court rejected the government's contention that the royalties imposed by the settlement and cross-licenses were so large as to exclude potential

(continued...)

The scope-of-the-patent test subjects settlements to antitrust scrutiny if the settlements (1) exceed the bounds of the patent monopoly, *United States v. Singer Mfg. Co.*, 374 U.S. 174, 196-97 (1963); (2) settle sham litigation, *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61 (1993); or (3) involve a patent obtained through fraud on the PTO. *Walker Process Equip., Inc., v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177 (1965).

The scope-of-the-patent approach creates a reasonably bright line between lawful and unlawful conduct, consistent with the need to have antitrust rules that are clear and explainable. *See Bell Tel. Co. v. linkLine Commc'ns*, 555 U.S. 438, 452 (2009) ("[w]e have repeatedly emphasized the importance of clear rules in antitrust law." The need for clear rules is magnified where the agreements subject to antitrust scrutiny are entered into to resolve inherently uncertain patent litigation. *See Whitmore v. Arkansas*, 495 U.S. 149, 159-60 (1990) ("It is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in this case."); *Asahi Glass Co. v. Pentech Pharms. Inc.*, 289 F. Supp. 2d

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[11](...continued)
competitors from using the patented processes and unreasonably restrained gasoline supply because "[t]his argument ignores the privileges incident to ownership of patents." *Id.* at 172.

986, 993 (N.D. Ill. 2003) (Posner, J.) ("No one can be *certain* that he will prevail in a patent suit.").

III.

THE FTC'S PROPOSED RULE IS PERNICIOUS

A. The FTC's Proposed Rule Creates Ambiguity.

The Question Presented as framed by the FTC ("Whether reverse-payment agreements are per se lawful unless the underlying patent litigation was a sham or the patent was obtained by fraud, or instead are presumptively anticompetitive and unlawful" *(See* FTC Br. I.)) completely disregards the traditional analysis of the legality of a patent settlement – whether the scope of the patent has been exceeded by the terms of the settlement.

The FTC urges an ambiguous and burdensome rule, which relies solely on the presence of a "payment" (a term the FTC does not define[12]) as

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[12] Virtually any patent settlement could be seen as involving a "payment" to the alleged infringer under the FTC's approach. While at one point the FTC mentions "monetary payment," *id.* 16; at another point it refers to "money *or similar consideration*," *id.* at 27 (emphasis added); later the FTC writes that the rule could also apply to "an alternative form of consideration" having similar effects to "direct payments." *Id.* at 36 n.7.

Even a license with no payment, either by the

(continued...)

the means of identifying supposedly anticompetitive patent litigation settlements[13], and is grounded on the unprecedented and mischievous premise that a patent is entitled to no weight at all unless and until it is proven through litigation to judgment to be valid and infringed. The FTC's rule would condemn many typical settlements both inside and outside the pharmaceutical context.

The rule would give the FTC unfettered discretion to challenge almost any settlement it

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[12](...continued)
patentee or the licensee, might be considered by the FTC, or alleged by a private plaintiff, to be a "payment" to the licensee if a "fair" royalty would have been, in their view, greater, or some other term of the license could have been different. The FTC's brief cites with approval C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 663-66 (2009), which describes numerous types of transactions that allegedly "disguise the fact of payment."

[13] The FTC's position is inconsistent with Department of Justice's position only a few years ago. Noting the "high degree of suspicion" of reverse-payments reflected in the FTC's approach, Brief for United States as Amicus Curiae, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273) (filed May 17, 2006), 2006 WL 1358441 at *12, the Department of Justice's view was that "the mere presence of a reverse payment in the Hatch-Waxman context is not sufficient to establish that the settlement is unlawful." *Id.* at *11.

believed could conceivably have been structured to provide more "consumer benefits."[14] The FTC's rule would also give *private* plaintiffs and their lawyers, with the incentive of possible treble damages and attorneys' fees, the same opportunity.[15] Such "second-guessing" and the threat of litigation is inimical to calculating the value to the patentee of its property rights in the patent and in R&D investment.

The FTC's proposed rule encourages litigation and its attendant expense and distraction for businesses on both sides of an IP dispute.

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[14] The FTC does not satisfactorily explain this *ipse dixit* conclusion.

[15] The burden of showing that the challenged agreement has a substantial anticompetitive effect ordinarily rests with the antitrust plaintiff. *United States v. Arnold, Schwinn & Co.*, 388 U.S. 365, 374 n.5 (1967), *overruled on other grounds by Cont'l T.V., Inc. v. GTE Sylvania, Inc.*, 433 U.S. 36, 58-59 (1977). Under the FTC's test, if an antitrust plaintiff alleges that (I) a settlement agreement provides for delayed entry into the market by the non-patentee, and (ii) the non-patentee defendant received a "payment," the settlement is presumptively unlawful and the burden shifts to the settling parties to prove that the "payment" was for something other than a "delay" in market entry. FTC Br. 37-38.

B. The FTC's Rule Discourages Settlement.

The FTC's rule would thwart the judicial policy favoring settlement and impose a significant and unwarranted burden on the judicial system. The FTC's rule restricts settlement options[16], chills settlements[17] and leads to protracted litigation, all contrary to greater societal interests. *See*

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[16] *See Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) ("A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive.").

[17] Settlements in complex commercial cases frequently include cooperative business dealings, such as exchanges of assets, including licensing or cross-licensing of intellectual property. In antitrust analysis, licenses divide markets among competitors. 12 Herbert Hovenkamp *et al.*, ANTITRUST LAW ¶ 2040b (1999) ("[Licensing] agreements would generally be classified either as per se unlawful naked price fixing, or as per se unlawful naked horizontal market divisions. . ." in the "absence of a patent."

Granting an exclusive license has long been thought to be one of the most legally important and secure rights of a patentee – it is an incident of the patentee's property interest. The Supreme Court held over a century ago that antitrust law does not prohibit "a restraint of commerce that may arise from reasonable and legal conditions imposed upon the ... licensee of a patent." *Bement v. Nat'l Harrow Co.*, 186 U.S. 70, 92 (1902).

Tamoxifen. 466 F.3d at 212 n.26 (a rule making patent litigation settlements "subject to the inevitable, lengthy and expensive hindsight of a jury as to whether the settlement constituted a 'reasonable' restraint . . . .would place a huge damper on such settlements contrary to the law . . . that settlements are not only permitted, they are encouraged."); *Cipro*, 363 F. Supp. 2d 514, 529 (E.D.N.Y. 2005) ("[M]aking the legality of a patent settlement agreement, on pain of treble damages, contingent on a later court's assessment of the patent's validity might chill patent settlements altogether."), *aff'd*, 544 F.3d 1323 (Fed. Cir. 2008).[18]

Compromise and settlement of disputed claims is favored by the courts. *See Williams v. First Nat'l Bank*, 216 U.S. 582, 595 (1910); *McDermott, Inc. v. AmClyde*, 511 U.S. 202, 215 (1994); *Schering-Plough*, 402 F.3d at 1072, 1075 (the general policy

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[18] The FTC recognizes that its rule would require relitigating the underlying patent dispute in private antitrust lawsuits. FTC Br. 40, but it favors this result because "in the aggregate, those judgments on the merits "will reflect results more in keeping with the policies of the antitrust laws, the Patent Act, and the Hatch-Waxman Amendments than if all the cases had been settled with reverse payments." *Id*. The FTC concedes, however, that any standard that requires relitigating the underlying patent dispute would be unmanageable and would create a "powerful disincentive to settlement." FTC Br. 54. The FTC dos not explain this paradox.

favoring settlements "extends to the settlement of patent infringement suits," and "[t]here is no question that settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation.")

As the FTC concedes, forcing relitigation of the merits of a patent case in a subsequent antitrust suit would create a "powerful disincentive to settlement" because litigants would know that by settling the patent dispute, they were inviting one or more antitrust cases. FTC Br. 54. Forcing relitigation would mitigate or negate entirely the benefits of settlement by having treble-damages antitrust liability depend on a subsequent court's analysis of what the outcome of highly technical and uncertain patent litigation might have been.

The presumption of illegality and shifting of the burden to defendants inherent in the FTC's proposed rule provides an incentive for private plaintiffs to file weak antitrust suits in hopes of proceeding to discovery and extracting a settlement of their claim, but it discourages settlement of the underlying patent dispute. This Court has recognized that "proceeding to antitrust discovery can be expensive," and the importance of "avoid[ing] the potentially enormous expense of discovery in cases with no reasonably founded hope that the discovery process will reveal relevant evidence to support a [Section] 1 claim." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558-59 (2007) (internal quotation omitted). In those cases that

survive dispositive motions, courts and the parties will have to re-try the merits of the patent suit that the parties (and probably the judge) had hoped were settled.

Despite acknowledging that it would be undesirable and unworkable to relitigate the patent merits in a subsequent antitrust case, the FTC recognizes that its proposed rule would have precisely that effect in private antitrust actions for "[q]uantification of damages." FTC Br. 55 n.11. Private antitrust actions far outnumber those brought by the FTC and will be subject to whatever test the Court adopts in this case.[19]

C. The FTC Rule Discourages Innovation.

Although the FTC recognizes the importance of "preserv[ing] the incentives to innovate that benefit consumers in the long run," FTC Br. 45, it proposes a rule that would discourage innovation. *See Tamoxifen*, 466 F.3d at 203 ("Rules severely restricting patent settlements might also be contrary to the goals of the patent laws because the increased number of continuing lawsuits that would result would heighten the uncertainty surrounding patents and might delay innovation."); *Schering-Plough Corp. v. FTC*, 402

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[19] In fact, relitigating the patent case would occur in all cases because no conclusion about a patent settlement's effect on competition could logically be reached without determining if the patent was valid and infringed.

F.3d 1056, 1073 ("the caustic environment of patent litigation may actually decrease product innovation by amplifying the period of uncertainty around the drug manufacturer's ability to research, develop, and market the patented product or allegedly infringing product"); *see Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294, 1308 (11th Cir. 2003) ("restricting settlement options, which would effectively increase the cost of patent enforcement . . . would impair the incentives .. . and innovation"). The FTC's approach would have harmful long-term effects on innovation, and is not only legally wrong, but is bad policy. *See* Frank H. Easterbrook, *Ignorance and Antitrust*, in Thomas M. Jorde & David J. Teece, eds., *Antitrust, Innovation, and Competitiveness*, 119, 122-23 (1992) ("[a]n antitrust policy that reduced prices by 5 percent today at the expense of reducing by 1 percent the annual rate at which innovation lowers the cost of production would be a calamity. In the long run a continuous rate of change, compounded, swamps static losses.")

The uncertainty created by the FTC's ambiguous and burdensome rule would have a chilling effect on innovation and, consequently, the United States' economy and its competitiveness in the global economy, and would impose unwarranted burdens upon the judicial system.

The scope-of-the-patent approach is a clear and doctrinally sound method for analyzing patent

litigation settlements. Equally important, it creates readily discernable criteria, and does not vest virtually unlimited discretion in the FTC to commence proceedings challenging settlements. To the world of industry and commerce, minimizing legal and regulatory uncertainty is an important virtue, allowing business to gauge accurately the risks and rewards of investment in innovation.

CONCLUSION

For the foregoing reasons, the judgment of the Court of Appeals should be affirmed.

February 27, 2013

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AMICUS CURIAE BRIEF

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v.

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ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES AS AMICUS CURIAE IN SUPPORT OF PETITIONER

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BRIEF FOR THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES AS AMICUS CURIAE IN SUPPORT OF PETITIONER

INTEREST OF AMICUS CURIAE[1]

The National Association of Chain Drug Stores ("NACDS") represents 123 chain members, including traditional drug stores, supermarkets, and mass merchants with pharmacies—from regional chains

[1] No person other than *amicus curiae* or its counsel authored this brief in whole or in part or made a monetary contribution intended to fund its preparation or submission. The parties have consented to the filing of this brief and such consents are being lodged herewith.

with four stores to national companies. These members operate more than 41,000 pharmacies in the United States and provide jobs for more than 3.8 million employees, including 132,000 pharmacists. With annual sales of more than $1 trillion, NACDS members account for approximately 6.6% of U.S. gross domestic product. They fill more than 2.7 billion prescriptions annually, some 72% of U.S. prescriptions.

NACDS members and their patients are directly affected by anticompetitive exclusion payment agreements. Exclusion payments maintain artificially high prices for prescription drugs, undermining NACDS members' efforts to bring quality prescription pharmaceuticals to patients at competitive prices. NACDS has been a determined critic of exclusion payments for more than a decade, having filed nine amicus briefs seeking adequate antitrust scrutiny of exclusion payments in six appellate cases and in this Court. NACDS is uniquely positioned to bring pertinent issues and facts to the Court's attention.

SUMMARY OF ARGUMENT

Other amicus briefs address in detail the economic and patent law principles that support the FTC's antitrust analysis. While touching those principles lightly, this brief focuses on the terms, structure, and history of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. § 355 (2012)) [hereafter the "Hatch-Waxman Act"]. The Eleventh Circuit's "scope of the patent" test is entirely incompatible with the Act's: (1) 180-

day-exclusivity "bounty" for generics to enter the market by invalidating or inventing around a pharmaceutical patent; and (2) automatic exclusion of generics, under certain conditions, for up to 30 months. A payment from the patentee that countermands the statutory incentive for generics to challenge patents, and that secures exclusion beyond 30 months, contradicts the Act.

We also refute in detail the suggestion that exclusion payments are somehow a "natural byproduct" of the Hatch-Waxman Act. *Contra In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 206 (2d Cir. 2005), *cert. denied*, 551 U.S. 1144 (2007); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1074 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006). The notion seems to be that Congress unintentionally deprived brand manufacturers of an ability to settle patent cases by means of waiving potential patent-infringement damages against generics, and that consequently patentees can settle these cases only by making exclusion payments. No aspect of that notion is correct. Congress did not prevent patentees from waiving damage claims against generics; instead, Congress gave patentees the *choice* to either sue the generic manufacturer for damages, and thereby have the ability to waive the damage claim in settlement, or forgo that option in favor of getting automatic exclusion of the generic drug from the market for 30 months. The legislative history reveals that Congress granted patentees this choice quite intentionally. Even when the patentee chooses the automatic 30-month stay, nothing in Hatch-Waxman requires or encourages patentees to settle patent cases by making exclusion payments rather than granting early-entry licenses.

Exclusion payments thus are not a "natural by-product" of the Act, but a subversion of it. The brand manufacturers acknowledged as much in 2003 when they convinced Congress that it could put an end to exclusion payment agreements simply by requiring that they be produced to the antitrust agencies for prosecution under the Sherman Act. Such reporting was sufficient, testified brand manufacturer representatives, because the agreements are unlawful under the Sherman Act—exclusion payments "would have been violations of the antitrust laws and/or the patent laws whether the Hatch-Waxman Act existed or not." *Generic Pharmaceuticals: Marketplace Access and Consumer Issues: Hearing Before S. Comm. on Commerce, Sci., and Transp.*, 107th Cong. 71 (2002) (remarks of Gregory J. Glover).[2] They were right.

ARGUMENT

I. THE COURT OF APPEALS MISAPPREHENDED PATENT LAW AND THE BASIC ECONOMICS OF EXCLUSION PAYMENTS.

The Court of Appeals assumed away the legal and economic question posed by exclusion payments in the pharmaceutical industry. The Court held that, "Because the patent had that potential [to exclude generics] at the time of settlement, we treat[] the holder as though it had an exclusionary right at that

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[2] A chart identifying the principal legislative history of the relevant portions of the legislation discussed in this brief is included as an Appendix.

time." Pet. App. 20a; *see also Schering-Plough*, 402 F.3d at 1066 ("By virtue of its '743 patent, Schering obtained the legal right to exclude [generics] from the market...."). If one starts with the premise that a patentee has an absolute right to exclude all competitors for the term of the patent, one might well conclude that it is not anticompetitive for the patentee to pay all competitors to stay out of the market for the duration of that term. *But see eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 394 (2006) (even after a final judgment of infringement, the patentee can get a permanent injunction only by satisfying the traditional requirements for equitable relief).

The problem is that the Court of Appeals' premise is incorrect. When the litigants entered into the exclusion payment agreement, the very issue they were contesting in the patent case was *whether* the patentee had a "right to exclude" the generic. The appeals court thus disregarded Justice Holmes' admonition, frequently reemphasized by the Court, that, "the word 'right' is one of the most deceptive of pitfalls; it is so easy to slip from a qualified meaning in the premise to an unqualified one in the conclusion. Most rights are qualified." *Am. Bank & Trust Co. v. FRB*, 256 U.S. 350, 358 (1921); *see also Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 601 (1985); *Lorain Journal Co. v. United States*, 342 U.S. 143, 155 (1951).

The Court of Appeals did acknowledge that the patentee's right to exclude is qualified by the patent's temporal scope. Pet. App. 24a-25a. But the requirement that patents be kept within their temporal scope is just "one obvious manifestation" of the public interest with which patents are affected.

Blonder-Tongue Labs. v. Univ. of Ill. Found., 402 U.S. 313, 343 (1971). The Court of Appeals ignored a second such manifestation—"[a] second group of authorities [that] encourage authoritative testing of patent validity." *Id.* at 344; *see also In re K-Dur Antitrust Litig.*, 686 F.3d 197, 215–16 (3d Cir. 2012) (citing numerous cases), *petitions for cert. pending*, No. 12-245 (filed Aug. 24, 2012) and No. 12-265 (filed Aug. 29, 2012); *accord Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969) (patentee cannot "muzzle[]" those who have an "economic incentive to challenge the patentability of an inventor's discovery"); *United States v. Singer Mfg. Co.*, 374 U.S. 174, 200 (1963) (White, J., concurring) (settlement of patent interference was unlawful because it reflected "collusion among applicants to prevent prior art from coming to or being drawn to the [PTO's] attention"); *United States v. Line Material Co.*, 333 U.S. 287, 319 (1948) (Douglas, J., concurring) (patentee cannot lawfully create "a powerful inducement for the abandonment of competition, for the cessation of litigation concerning the validity of patents, for the acceptance of patents no matter how dubious, for the abandonment of research in the development of competing patents"); *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1298 (S.D. Fla. 2005) ("[A]ny construction of the patent's exclusionary scope ... that fails to take into account the chances of the patent being held invalid would essentially afford pioneer drug manufacturers an unbridled power to exclude others without regard to the strength of their patent rights.").

With the notable exceptions of pharmaceutical and chemical patents, the vast majority of issued patents have little economic significance. So it is effi-

cient to have a patent process consisting of patent issuance based on an ex parte PTO proceeding, followed by judicial review of the comparatively few patents that turn out to have genuine economic significance. *See* Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 Nw. U. L. Rev. 1495, 1497 (2001). This efficient system would be entirely undermined if patentees who have gotten only halfway through the process—the ex parte part—were permitted to pay their would-be competitors to forgo the inter se part.

The Third Circuit's analysis of exclusion payments is faithful to both aspects of the public interest in patents, *i.e.*, the need to keep them within their temporal scope and to subject them to judicial testing. *K-Dur*, 686 F.3d at 214–216. That analysis is founded on the economic concept of "expected" litigation outcomes: the patentee would not make a payment to the generic, and the generic would not require such a payment, unless it resulted in less competition than each of them expected to result from the litigation. Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. of Econ. 391, 407–08 (2003) [hereafter "Shapiro, *Antitrust Limits*"]; Herbert Hovenkamp, et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1759 (2003) [hereafter "Hovenkamp, *Anticom-*

petitive Settlement"].[3] In the Third Circuit's formulation, the reasonable economic inference is that the brand's payment represents a quid pro quo for later entry than the litigants otherwise expected. *K-Dur*, 686 F.3d at 214–216.

The economics are made clear by considering licensed-entry agreements, which the FTC and private plaintiffs generally do *not* contend violate the Sherman Act. Assume that the generic manufacturer entered the market for two years of the remaining seven years of the patent term. The brand manufacturer offers to waive the potential patent infringement damages if the generic manufacturer will immediately withdraw from the market. This is simply a particular type of early-entry license—a retrospective license. Such a license does not offend the public policy in favor of judicial testing of patents, because such testing is not an end in itself but simply a means of ensuring that the public does not suffer from unwarranted patent-based monopolies. *See, e.g.*, *Blonder-Tongue Labs.*, 402 U.S. at 343; *Lear*, 395 U.S. at 670. Licensed-entry settlements—without exclusion payments—do not offend this policy because (absent other anticompetitive provisions) they liquidate and deliver to consumers their expected savings from the patent litigation. *See* Shapiro, *Antitrust Limits*, at 397–99.

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[3] The economics literature on "expected" outcomes of litigation goes back decades. *See, e.g.*, William M. Landes, *An Economic Analysis of Courts*, 14 J.L.& Econ. 61 (1971); George L. Priest & Benjamin Klein, *The Selection of Disputes for Litigation*, 13 J. Legal Stud. 1 (1984); Robert T. Cooter & Daniel L. Rubinfeld, *Economic Analysis of Legal Disputes*, 27 J. of Econ. Lit. 1067 (1989).

Now assume, however, that the generic manufacturer in the example above concludes that, given its view of the patent's strength, two years of profits are not enough—that its potential gains from winning, discounted by the risk of losing, mandate more than two years' worth of profits. So the generic manufacturer demands that the brand manufacturer waive potential damages for the first two years and also either grant a prospective license for three additional years on the market or make an exclusion payment representing (at least) three years' worth of the generic's profits. If the brand manufacturer makes the exclusion payments, consumers clearly have been denied additional expected competition. Otherwise, the generic manufacturer would not have required the payments, and the brand manufacturer would not have made them. Also clear is that the brand manufacturer excluded the generic competitor for the additional time based not on the strength of the patent, but on a sharing of the brand's monopoly profits.

It is true, of course, that to achieve settlement the patentee must transfer *some* consideration to the generic manufacturer. But from an antitrust perspective it matters profoundly what form that consideration takes. When the "coin" of settlement is limited to licensed entry, the generic manufacturer's economic interests stay aligned with those of consumers—both want the earliest entry that is feasible given the patent's strength. Exclusion payments, in contrast, sever the link between those interests: the generic manufacturer accepts the payments as a substitute for the profits that it would have earned by competing—and generating consumer savings—for a period of time commensurate with the

patent's strength. This severance is the hallmark of anticompetitive conduct. *Premier Elec. Constr. Co. v. Nat'l Elec. Contractors Ass'n*, 814 F.2d 358, 369 (7th Cir. 1987).

II. EXCLUSION PAYMENTS CONFLICT WITH THE TERMS, STRUCTURE, AND HISTORY OF THE HATCH-WAXMAN ACT.

The Hatch-Waxman Act was compromise legislation in which the generic manufacturers received, among other things, exemption from having to duplicate costly clinical trials and other studies in order to garner FDA approval, 21 U.S.C. § 355(j)(2)(A)(iv) (generic need only prove that it is "bioequivalent" to the pioneer drug); and the brand manufacturers received, among other things, restoration of some of the patent term that expires as they await FDA approval, H.R. Rep. No. 98-857, pt. 1, at 15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647–48 [hereafter "House Report pt. 1"]. *See generally Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 671, 676–78 (1990) (describing essential compromise); 130 Cong. Rec. H8701, at H8706 (daily ed. August 8, 1984) (remarks of Rep. Waxman) (same); 130 Cong. Rec. S6978–79 (daily ed. June 12, 1984) (statement of Sen. Hatch) (same). The Act resulted from "a unique legislative process which, in reality, was a congressionally supervised negotiation between the generic and brand-name pharmaceutical industries in which the parties were compelled to reach a compromise by the legislature." Alfred B. Engelberg, *Special Patent Provisions for Pharmaceu-*

ticals: Have They Outlived Their Usefulness?, 39 IDEA J.L. & Tech. 389, 391 (1999) [hereafter "Engelberg, *Special Patent Provisions*"]; *see also* 130 Cong. Rec. H9105, at H9116 (daily ed. Sept. 6, 1984) (remarks of Rep. Waxman) (the Act reflects a compromise that "has been signed off on by the original drug manufacturers, Pharmaceutical Manufacturers Association, the generic drug manufacturers, and the consumers and the elderly . . . .").[4]

Exclusion payments are entirely incompatible with the Hatch-Waxman Act's fundamental provisions. The Act extended the terms of pharmaceutical patents in certain circumstances, but also created specific incentives for generics to enter the market by invalidating or inventing around those patents. The Act also limited the patentee's ability to get automatic exclusion of competition—exclusion without regard to the patent's strength—to 30 months, with Congress rejecting arguments that the presumption of patent validity mandated such exclusion for the patent's entire term. Some courts have nevertheless suggested that exclusion payments are lawful because they are a "natural by-product" of the increased incentive for generic entry and the limit on automatic exclusion. It is *always* "natural" or "rational" for incumbent manufacturers with market power to pay potential competitors not to enter the market. That's why we have the Sherman Act.

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[4] The brand manufacturers' trade association was then known as the Pharmaceutical Manufacturers Association, or "PMA." That association is now known as the Pharmaceutical Research and Manufacturers of America, or "PhRMA."

A. The 180-Day Bounty

The Hatch-Waxman Act intended to speed generics onto the market not only by easing the FDA approval process, but also by facilitating patent litigation between brand and generic manufacturers. *See* House Report pt. 1, at 14–17; H.R. Rep. No. 98-857, pt. 2, at 5–6 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2689–90 [hereafter "House Report pt. 2"]. The Act thus provides a financial "bounty" for a generic that invalidates or designs around a brand patent: the first generic manufacturer to file a paragraph IV certification is entitled to 180-day exclusivity, during which time the FDA cannot approve any other Abbreviated New Drug Application (ANDA) for the same drug. 21 U.S.C. § 355(j)(5)(B)(iv).[5]

Before the Hatch-Waxman Act, generic manufacturers had insufficient incentive to bring costly patent-validity challenges. A finding of invalidity would benefit not only the successful litigant, but also every potential generic manufacturer, *Blonder-Tongue Labs.*, 402 U.S. at 346–347, thus creating a significant "free-rider" problem, Joseph S. Miller, *Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents*, 19 Berkeley Tech. L.J. 667, 725 (2004). The 180-day exclusivity bounty, which can be worth hundreds of millions of dollars for the

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[5] Before 1998, the FDA's "successful defense" requirement resulted in relatively few generics being awarded 180-day exclusivity. *See* FTC, *Generic Drug Entry Prior to Patent Expiration* 57 (July 2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf [hereafter "FTC Study"]. After the courts overturned that requirement, generic manufacturers were awarded exclusivity much more often and responded by filing many more ANDAs with Paragraph IV certifications. *Id.*

"first-filer" on a blockbuster drug, overcomes the free-rider problem.

Congress plainly intended this statutory bounty "to encourage litigated challenges by generic manufacturers against the holders of weak or narrow patents." *K-Dur*, 686 F.3d at 217. And "[t]hat goal is undermined by application of the scope of the patent test which entitles the patent holder to pay its potential generic competitors not to compete." *Id.*

Notably, a generic manufacturer can collect this statutory bounty only by entering the market and selling a low-priced product to consumers. The bounty is not a cash payment from the government treasury, but a period of generic exclusivity *in the marketplace*. The generic manufacturer gets a bounty only to the extent that consumers also benefit. The point of the bounty was not to enrich generics, but "to get generic drugs into the hands of patients at reasonable prices—fast." *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991).

Some courts have nevertheless suggested that exclusion payments should be permitted because they increase generics' incentives to bring patent challenges. *See, e.g.*, *Tamoxifen*, 466 F.3d at 206; *Schering-Plough*, 402 F.3d at 1075. This argument is "perverse." Herbert Hovenkamp, et al., *Balancing Ease and Accuracy In Assessing Pharmaceutical Exclusion Payments*, 88 Minn. L. Rev. 712, 716 (2004). True, permitting exclusion payments would increase the generic manufacturer's incentive to *initiate* patent challenges—potential earnings from a shared monopoly are greater than those from competition. But if exclusion payments were permitted, brand and generic manufacturers would use them to terminate not only the additional (marginal) chal-

lenges prompted by the increased reward, but also all the inframarginal challenges. *See* Keith Leffler & Cristofer Leffler, *Efficiency Trade-Offs in Patent Litig. Settlements: Analysis Gone Astray?*, 39 U.S.F. L. Rev. 33, 44 (2004). Consumers get savings not when generics initiate a patent challenge, but when they use it to enter the market by prevailing in the patent litigation or obtaining an early-entry license. Payments in exchange for exclusion result in more exclusion, not more entry.

B. The 30-Month Stay

Permitting exclusion payments would also contradict the Hatch-Waxman Act's 30-month-stay provision. *See* 21 U.S.C. § 355(j)(5)(B)(iii). That provision gives the patentee automatic exclusion, *i.e.*, government-enforced exclusion without judicial inquiry into the patent's strength. But after the 30 months expire, the FDA can approve the generic drug for marketing regardless of whether patent litigation is ongoing. *Id.* Thereafter the patentee can get exclusion only the old-fashioned way—by satisfying the requirements for a preliminary injunction, including a showing of likelihood of success on the merits. Indeed, even a patentee with a final judgment of validity and infringement does not get automatic exclusion. *eBay*, 547 U.S. at 392–93.

Congress could have granted automatic exclusion for the duration of pharmaceutical patents. Instead, Congress rejected just such an amendment, which would have prevented the FDA from granting approval to the generic unless and until a court had declared the patent invalid or not infringed. *See* House Report pt. 2, at 9–10. Congress concluded

that permitting the generic to enter before a court decision does *not* "overturn[] the statutory presumption of a patent's validity." House Report pt. 1, at 28; *see also* House Report pt. 2, at 60–61. Brand and generic manufacturers enjoy no antitrust immunity when they help themselves to a hiatus from competition that Congress refused to grant them.

C. The Bolar Amendment

Some courts have suggested that exclusion payments should get an antitrust pass because they are a "natural byproduct" of the Hatch-Waxman Act. *See Tamoxifen*, 466 F.3d at 206; *Schering-Plough*, 402 F.3d at 1074; *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003). The argument has two premises: (1) in prohibiting generic manufacturers from entering the market during the 30-month stay, and thus preventing them from becoming potentially subject to infringement liability, the Act deprives patentees of the ability to settle by waiving claims for potentially infringing sales; and (2) deprived of this traditional means of settling, brand manufacturers can settle Hatch-Waxman cases (or most such cases) only by making exclusion payments. *Tamoxifen*, 466 F.2d at 207; *Schering-Plough*, 403 F.3d at 1074–75; *Ciprofloxacin*, 261 F. Supp. 2d at 251–52. This argument is riddled with historical, logical, and economic flaws.

Three provisions of the Hatch-Waxman Act are relevant: (1) 35 U.S.C. § 271(e)(1), which provides that, "it shall not be an act of infringement to make, use, offer to sell, or sell . . . a patented invention . . . solely for use as reasonably related to the development and submission of information under a Federal

law which regulates the manufacturer, use, or sale of drugs . . . ." (a provision that ultimately became known as the "*Bolar* Amendment"); (2) 35 U.S.C. § 271(e)(2), which provides that the filing of an ANDA with a Paragraph IV certification is an act of infringement, thus providing federal courts with subject matter jurisdiction; and (3) the 30-month stay.

No Loss of Ability to Waive Damages. The first premise of the "natural byproduct" argument—that the Act deprives brand manufacturers of the ability to settle patent cases by means of waiving a claim for potentially infringing generic sales—simply misreads the statute. The Act prohibits the generic manufacturer from entering for 30 months, and thus from becoming potentially liable for infringing sales *if and only if* the patentee sues the generic manufacturer within 45 days after receiving the Paragraph IV certification. 21 U.S.C. § 355(j)(5)(B)(iii).

But this is entirely the patentee's choice. Rather than sue under the special provisions of 35 U.S.C. § 271(e)(2), a patentee retains the option to bring a traditional infringement claim under 35 U.S.C. § 271(a). *See, e.g.*, *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1341 (Fed. Cir. 2007). When a patentee elects not to sue under § 271(e)(2), the automatic 30-month stay does not apply, and the generic manufacturer can enter the market, and begin accumulating potential infringement liability immediately upon receiving FDA approval. 21 U.S.C. § 355(j)(5)(B)(iii). The patentee can then bring a traditional infringement case under 35 U.S.C. § 271(a) and enjoy the ability to transfer consideration to the generic manufacturer by waiving the potential damage claim.

Thus, the Hatch-Waxman Act does not prevent patentees from settling cases by waiving damage claims. The Act simply allows patentees to forgo that option in exchange for an automatic 30-month stay of competition. If patentees choose to automatically exclude generics from the market—and patentees do routinely choose that option—they can hardly complain that they consequently have no potential damages to waive.

No Unintentional Inability to Waive Damages. The "natural byproduct" argument also erroneously assumes that Congress *unintentionally* deprived patentees of their traditional ability to waive damage claims—that Congress did not understand the litigation dynamics that § 271(e)(2) would create. *See Ciprofloxacin*, 261 F. Supp. 2d at 252 (originating the argument by asserting that, "[T]he statutory scheme has the unintended consequence of altering the litigation risks of patent lawsuits. Accordingly, so-called reverse payments are a natural by-product of the Hatch-Waxman process...."). On the contrary, Congress knew full well that patentees that chose the benefits of § 271(e)(2) would forgo their traditional right to infringement damages.

The draft of the legislation released on April 4, 1984, contained the relevant language of § 271(e)(1) that is now known as the *Bolar* Amendment. *See* Engelberg, *Special Patent Provisions*, at 399. Section 271(e)(1) codified the holding of a then-recent district court decision that a generic's limited use of a patented drug in obtaining FDA approval did not constitute an act of infringement. *See Roche Products, Inc. v. Bolar Pharms. Co., Inc.*, 572 F. Supp. 255, 257 (E.D.N.Y. 1983). With respect to the pend-

ing legislation, "the PMA negotiators were of the view that the district court decision in *Bolar* did not change existing law and that codification of that decision merely preserved the status quo." Engelberg, *Special Patent Provisions*, at 399.

Before Congress voted on the bill, however, the Federal Circuit reversed the district court's holding in *Bolar*. *See Roche Products, Inc. v. Bolar Pharms. Co., Inc.*, 733 F.2d 858, 861 (Fed. Cir. 1984). This "unexpected reversal" caused "a major rift at the highest levels of PMA." Engelberg, *Special Patent Provisions*, at 401. A coalition of dissident PMA members came out against the legislation, arguing to Congress that the bill's patent-litigation provisions, including the *Bolar* Amendment, unfairly favored generics. *See, e.g., Innovation and Patent Law Reform: Hearings on H.R. 3285, H.R. 3286, and H.R. 3605 Before the Subcomm. on Courts, Civil Liberties, and the Admin. of Justice of the H. Comm. on the Judiciary*, 98th Cong. pt. 1, at 444 (1984) [hereafter "*Hearings*"]. The coalition argued that the bill improperly

- "institutionalize[d] and provide[d] incentive for a system of attacks on presumptively valid patents." *Id.* at 444 (Mem. of American Home Products, et al.); *see also* House Report pt. 1, at 71 (Minority View of Rep. Bliley) ("The patent provisions of this bill also encourage patent 'jumping' and litigation over the validity of patents.").
- effected an unlawful taking in violation of the Fifth Amendment by permitting generics to develop their products without incurring patent liability. *Hearings*, at 449

(statement submitted by coalition of brand manufacturers).

- allowed generic manufacturers to challenge patents while risking only the costs of litigation. *Id.* at 445; *see also id.* at 446 ("Their risk is slight because they will not have to invest in the research required for a complete NDA.").
- "withdr[e]w from the patentee his current right to collect damages from such infringement." *Id.* at 516–17 (statement of Norman Dorsen, on behalf of brand manufacturers).

Despite these arguments, Congress refused to alter the *Bolar* Amendment or the other patent-challenge provisions. Moreover, Congress rejected proffered compromise measures, such as permitting generics to conduct FDA-related tests during only the patent's last year, House Report pt. 2, at 8-9, or requiring generics to pay licensing fees to patentees for using their products to get FDA approval, *Hearings*, at 536. These alternatives conflicted with Congress' overriding objective to get generics on the market as quickly as possible. *See* House Report pt. 2, at 8–9.

But the brand manufacturers did not go away empty-handed. In exchange for ultimately acceding to the patent-challenge provisions, the PMA coalition demanded and received significant additional concessions. Congress extended the automatic stay, which originally was for 18 months, to 30 months, 130 Cong. Rec. H9105, at H9115, H9118 (daily ed. Sept. 6, 1984) (remarks of Rep. Waxman); 130 Cong. Rec. S10503, at S10504 (daily ed. August 10, 1984)

(remarks of Sen. Hatch), and granted market exclusivity for brand drugs that were not even protected by patents: five years of market exclusivity for "new chemical entities" ("NCEs"), and three years for drugs for which the manufacturer conducted new clinical studies, 21 U.S.C. §§ 355(c)(3)(D)(ii), (j)(5)(D)(ii); 21 U.S.C. §§ 355(c)(3)(D)(iii), (j)(5)(D)(iii); 35 U.S.C. § 156 (2012).[6] Congress granted these concessions specifically to mollify the dissident brand manufacturers that wanted to defeat the legislation in the wake of the *Bolar* appellate decision. *See, e.g.*, 130 Cong. Rec. S10503, at S10504 (daily ed. Aug. 10, 1984) (remarks of Sen. Hatch); Engelberg, *Special Patent Provisions*, at 405.

Thus, when the patentee opts to proceed under § 271(e)(2), the absence of a potential damage claim against the generics is hardly "unintentional." The patent-challenge provisions were part of the carefully considered, balanced compromise reached by Congress and the industry participants. The Act "is a compromise. As such, title II includes provisions about which PMA has had some reservations. The effects of these provisions were weighed very carefully by each of our companies. But while they cause concern, we recognize that they are the very fabric of the compromise of divided views and goals." *Hearings*, at 407 (testimony of PMA representative Robert J. Lewis).

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[6] At a rate of some two dozen NCEs per year, *see* FDA, *2011 Novel New Drugs* 2 (2012), *available at* http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DrugInnovation/UCM293663.pdf, these non-patent exclusivities are worth billions of dollars to brand manufacturers annually.

No Inability to Settle. The second premise of the "natural byproduct" argument—that brands that choose the § 271(e)(2) option can settle Hatch-Waxman cases only by making exclusion payments—is also wrong. True, brands that have elected the 30-month stay cannot transfer consideration to generics by waiving a potential damage claim. But neither can patentees in traditional, non-pharmaceutical patent litigation who have requested and received a preliminary injunction.

Nothing in the Hatch-Waxman Act changes these settlement dynamics. Just as in other, non-pharmaceutical patent cases, the litigants can settle the case with an early-entry license. Nothing in Hatch-Waxman requires consideration to take the form of an exclusion payment rather than a license. *Contra Schering-Plough*, 402 F.3d at 1074 (asserting that the Act "explains the flow of settlement funds," without addressing whether the consideration need be "funds" rather than a license).

Indeed, no theoretical or empirical analysis supports the notion that any significant number of § 271(e)(2) patent cases can be settled only by the brand manufacturer's paying the generic manufacturer. Instead, a detailed economic model, which has stood unchallenged for nearly a decade, shows that essentially all such cases that can be settled can be settled without an exclusion payment. *See* Keith Leffler & Cristofer Leffler, *Settling the Controversy Over Patent Settlements: Payments By the Patent Holder Should Be Per Se Illegal*, 21 Res. in L. & Econ. 477, 486 (2004). Those economics are confirmed by real-world experience in which, after an initial antitrust crackdown (subsequently softened),

brand and generic manufacturers continued to settle the cases—they simply settled with early-entry licenses rather than exclusion payments. *See Paying Off Generics to Prevent Competition with Brand Name Drugs: Should It Be Prohibited?: Hearing on S. 316 Before the Comm. on the Judiciary*, 110th Cong. 139 (2007) (prepared statement of the FTC) [hereafter "FTC Statement"].

No Justification. Nor are exclusion payments justified because the manufacturers find it "rational" to make and accept them. *Contra Tamoxifen*, 466 F.3d at 209; *Schering-Plough*, 402 F.3d at 1074–75. That competitors have an increased incentive to make anticompetitive pacts does not render them lawful. *See* Hovenkamp, *Anticompetitive Settlement*, at 1758. For example, if Congress granted special tax incentives for additional entry into an underserved market, the incumbent manufacturers would find it "rational" to pay the potential new competitors not to enter. But the conspirators could not justify the payments by arguing that Congress' tax policy increased the incentive to make them. *See, e.g., American Needle, Inc. v. NFL*, 130 S. Ct. 2201, 2213 (2010) ("But illegal restraints often are in the common interests of the parties to the restraint, at the expense of those who are not parties.").

Here Congress specifically incentivized generic entry by easing regulatory burdens and offering the 180-day exclusivity bounty. That Congress created such incentives for entry is a reason to subject exclusion payments to strict antitrust scrutiny, not to excuse them as a "natural byproduct" of the incentives.

III. SUBSEQUENT LEGISLATIVE HISTORY CONFIRMS THE UNLAWFULNESS OF EXCLUSION PAYMENTS.

The history of amendments to the Hatch-Waxman Act confirms that exclusion payments conflict with the Act. When Congress worked to prevent exclusion payments in 2003, the brand manufacturers warded off more stringent remedial legislation by arguing that the payments were already unlawful under the Sherman Act. Congress therefore solved the problem (or so it thought) by simply requiring that manufacturers produce all exclusion payment agreements to the FTC and DOJ so those agencies could prosecute under the Sherman Act.

On March 16, 2000, the FTC filed complaints in two administrative proceedings charging that drug manufacturers had unlawfully used exclusion payments to delay generic competition to the drugs Cardizem CD and Hytrin. Press Release, *FTC Charges Drug Manufacturers with Stifling Competition in Two Prescription Drug Markets* (Mar. 16, 2000), *available at* http://www.ftc.gov/opa/2000/03/hoechst.shtm. [7] Three months later, a district court in a private antitrust case held that the agreement concerning Card-

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[7] The FTC eventually filed final consent orders in both cases. *See Abbott Labs.*, Agreement Containing Consent Order, File Nos. 981 0395, *available at* http://www.ftc.gov/os/2000/03/abbottagreement.htm and http://www.ftc.gov/os/2000/03/genevaagre.htm; *Hoechst Marion Roussel, Inc.*, Agreement Containing Consent Order, Docket No. 9293 (Apr. 4, 2001), *available at* http://www.ftc.gov/os/adjpro/d9293/010404acco.pdf.

izem CD was per se unlawful. *See In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 682, 699 (E.D. Mich. 2000), *aff'd*, 332 F.3d 896 (6th Cir. 2003).

Shortly after the FTC filed its complaints, Congressional leaders began considering remedial amendments to prohibit the abuses that the FTC and private plaintiffs had uncovered. *See, e.g.*, 146 Cong. Rec. S7908 (July 27, 2000) (statement of Sen. Leahy) (introducing the Drug Competition Act ("DCA") in response to "two recent antitrust actions by the [FTC] and a related federal court decision" that "exposed" that "[m]anufacturers of patented drugs are paying tens of millions of dollars to manufacturers of generic drugs if they agree to keep products off the market" and "split[ting] the profits from maintaining a monopoly at the consumer's expense"). Over the next three years, Congress held multiple hearings regarding the proper legislative response to exclusion payment agreements.

The Hatch-Waxman Act's co-sponsors strongly condemned the agreements. *See, e.g.*, 148 Cong. Rec. S7565, at S7566 (daily ed. July 30, 2002) (remarks of Sen. Hatch) ("I find these types of reverse payment collusive arrangements appalling"); 148 Cong. Rec. S7342, at S7348 (daily ed. July 25, 2002) (remarks of Sen. Hatch) (approvingly quoting another participant in the 1984 negotiations of the Act as saying "[i]t was and is very clear that the law was not designed to allow deals between brand and generic companies to delay generic competition"); *id.* ("The FTC is doing the right thing in taking enforcement actions against those who enter anti-competitive agreements that violate our Nation's antitrust laws."); 146 Cong. Rec. E1538 (daily ed. Sept. 20, 2000) (remarks of Rep. Waxman) (exclusion pay-

ments are a "grossly anticompetitive abuse by branded and generic drug companies of the generic approval process"); *Examining Issues Related to Competition in the Pharmaceutical Marketplace: A Review of the FTC Report, Generic Drug Entry Prior to Patent Expiration: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 107th Cong. 6 (2002) (remarks of Rep. Waxman) (exclusion payments "have taken a provision of the Hatch-Waxman law and turned it on its head. The provision was to encourage competition. They have used it to discourage competition, in fact, to stop competition...").

The proposals that Congress considered were intended to prevent exclusion payment agreements. *See, e.g.*, 146 Cong. Rec. E1538 (daily ed. Sept. 20, 2000) (remarks of Rep. Waxman) (DCA designed to "prevent" collusive deals like those challenged by the FTC in the Hytrin and Cardizem cases "from recurring"); 147 Cong. Rec. S3711, at S3761 (daily ed. Apr. 6, 2001) (statement of Sen. Leahy) (reintroducing the DCA in the 107th Congress and emphasizing "the need to pass legislation to prevent [exclusion payment agreements] from happening in the future"); S. Rep. No. 107-167, at 4 (2002) (emphasizing the "need" to "put an end to [exclusion payment agreements'] exploitation" of the Hatch-Waxman Act); 148 Cong. Rec. S7618, at S7646 (daily ed. July 31, 2002) (remarks of Sen. Leahy) (DCA is the "solution to the problem of 'sweetheart' deals between brand name and generic drug manufacturers that keep generic drugs off the market, thus depriving consumers of the benefits of quality drugs at lower prices").

During the ensuing hearings, drug manufacturer representatives forestalled more forceful Congressional action by acknowledging that exclusion payments are already unlawful under the Sherman Act. For example, the brand manufacturers' official representative testified that "those cases [*i.e.*, the FTC complaints involving Cardizem CD and Hytrin] outline facts and presented facts that would have been violations of the antitrust laws and/or the patent laws whether the Hatch-Waxman Act existed or not." *Generic Pharmaceuticals: Marketplace Access and Consumer Issues: Hearing Before S. Comm. on Commerce, Science, and Transp.*, 107th Cong. 71 (2002) (remarks of Gregory J. Glover); *see also id.* at 85 (framing the issue as: "Do [exclusion payments] suggest that there need to be changes in the Hatch Waxman Act, or do they suggest that we already have the legal and statutory authority to take care of these so-called abuses through the antitrust laws?"); *Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements: Hearing Before S. Judiciary Comm.*, 107th Cong. 47 (2001) (statement of PhRMA) (exclusion payments are a "prime example of an alleged defect" in the "Hatch-Waxman Act [that] can be addressed under existing law without amending Hatch-Waxman"); *Recent Developments Which May Impact Consumer Access to, and Demand For, Pharmaceuticals: Hearing Before the Subcomm. On Health of the H. Comm. on Energy and Commerce*, 107th Cong. 51–52 (2001) (statement of Gregory J. Glover) ("The actions of the [FTC] in challenging some recent settlements demonstrate that the anti-trust authorities are actively and adequately monitoring settlements between partner companies and generic manufacturers.

Accordingly, there is no need to amend the Waxman-Hatch Act to deal with this issue."); *Closing the Gaps in Hatch-Waxman: Assuring Greater Access to Affordable Pharmaceuticals: Hearing Before the S. Comm. on Health, Ed., Labor, and Pensions*, 107th Cong. 55 (2002) (prepared statement of Gregory J. Glover) ("Ample means exist to assess any potentially inappropriate practices and to deter abuses" regarding exclusion payments); *Legislative and Regulatory Responses to the FTC Study on Barriers to Entry in the Pharmaceutical Marketplace: Hearing Before the S. Comm. on the Judiciary*, 108th Cong. 26 (2003) (statement of Bruce N. Kuhlik) (referring to a report of FTC actions against exclusion payments: "We believe that the FTC report vindicates our longstanding view that legislation to amend the Act in a manner adverse to research and innovation is unnecessary").

Given these admissions by drug manufacturer representatives, and the then-unanimous views of the competition regulators and the courts, Congress agreed that applying existing antitrust laws was sufficient to prevent future exclusion payments. Indeed, by the time the committee report for the DCA was issued on June 20, 2002, a district court had held that the exclusion payments concerning Hytrin were also per se unlawful. *In re Terazosin Hydrochloride Antitrust Litig.*, 164 F. Supp. 2d 1340, 1349 (S.D. Fla. 2000), *rev'd, Valley Drug Co. v. Geneva Pharms., Inc.*,

344 F.3d 1294 (11th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004).[8]

Congress therefore merely required that manufacturers produce all exclusion payment agreements to the federal competition regulators so that they could bring enforcement actions. *See* Medicare, Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, §§ 1111–1118, 117 Stat. 2066, 2448–64 (codified as amended in scattered subsections at 21 U.S.C. § 271, 355, 355a (2012)). Introducing an early version of the legislation, Drug Competition Act of 2000, S. 2993, 106th Cong. (2000),[9] Senator Leahy explained that, "The companies have been able to get away with this by signing secret deals with each other not to compete .... This [bill] solves the most difficult problem faced by federal investigators—finding out about the improper deals." 146 Cong. Rec. S7908 (daily ed. July 27, 2000) (remarks of Sen. Leahy); *see also* 146 Cong. Rec. E1538 (daily ed. Sept. 20, 2000) (remarks of Rep. Waxman) (disclosure of "sweetheart deals" to the FTC and DOJ "would enable Federal authorities to ensure that existing antitrust and drug approval laws are enforced to the letter").

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[8] A week after the DCA committee report, an administrative law judge issued an opinion finding that the exclusion payment in the K-Dur matter was lawful. The FTC staff immediately appealed that outlier decision to the full Commission, which ultimately reversed it. *In re Schering-Plough Corp.*, FTC Docket No. 9297 (June 27, 2002), *rev'd*, 136 F.T.C. 956 (2003). The Eleventh Circuit later reversed the Commission.

[9] Similar bills, H.R. 5313 and H.R. 5235, were also introduced in the House during the 106th Congress, but were not reported out of committee.

Congress ultimately combined the DCA's reporting provisions with other Hatch-Waxman Act reforms aimed at curbing manufacturers' abuses.[10] Although multiple iterations of the Greater Access to Affordable Pharmaceuticals Act were introduced in successive Congresses before its eventual passage as part of the MMA in 2003, GAAP's essential purposes were always to prohibit brand manufacturers from invoking multiple 30-month stays by listing and suing on multiple patents,[11] and to prohibit generic manufacturers from indefinitely "parking" the 180-day exclusivity in exchange for an exclusion payment. *See, e.g.*, Issue Brief for Congress, "The Hatch Waxman Act: Proposed Legislative Changes

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[10] After the DCA died in committee, Senator Leahy reintroduced it as S. 754 in the 107th Congress, 147 Cong. Rec. S3711, at S3760–61 (daily ed. Apr. 6, 2001), with a companion bill being introduced in the House as H.R. 1530. The DCA was reported favorably out of the Senate Judiciary Committee, S. Rep. No. 107-167, at 4, 5 (2002), and on November 18, 2002 it passed the Senate with an amendment by unanimous consent, 148 Cong. Rec. S11339, at S11341–11342 (daily ed. Nov. 18, 2002). After the House failed to act on the legislation, it was introduced again in the 108th Congress as S. 946. *See* 149 Cong. Rec. S5486, at S5493 (daily ed. Apr. 29, 2003).

[11] The 30-month stay was subject to widespread abuse as brand manufacturers filed seriatim infringement suits, each addressing a different patent, thereby availing themselves of multiple 30-month stays. FTC Study, at 39–46.

Affecting Pharmaceutical Patents," Updated Nov. 25, 2002, at 8-9.[12]

The changes to Hatch-Waxman in the MMA are found in Title XI, Access to Affordable Pharmaceuticals. MMA §§ 1101–1118 (codified at 21 U.S.C. §§

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[12] The Senate passed the GAAP legislation, S. 812, on July 31, 2002, but it died in the 107th Congress (as did similar legislation in the House, H.R. 5272 and H.R. 5311) when the House failed to act. *See* Erika K. Lietzan, *A Brief History of 180-day Exclusivity Under the Hatch Waxman Amendments to the Federal Food, Drug, and Cosmetic Act*, 59 Food & Drug L.J. 287, 309–10 (2004). GAAP was reintroduced in the 108th Congress as S. 54 and as Title II to S. 7, The Prescription Drug Benefit and Cost Containment Act of 2003. *See* Greater Access to Affordable Pharmaceuticals Act, S. 54, 108th Cong. (2003); Prescription Drug Benefit and Cost Containment Act, S. 7, 108th Cong. (2003). An amended version was introduced as S. 1225. *See* Lietzan, *supra* at 310. H.R. 2491, the House version of S. 1225, was introduced on June 17, 2003. *See* Greater Access to Affordable Pharmaceuticals Act, H.R. 2491, 108th Cong. (2003). After S. 1225 passed out of the Senate HELP committee by unanimous consent, the Senate adopted a narrowed version of it as an amendment to S. 1. *See* Lietzan, *supra* at 310. On June 25, 2003, the Senate also adopted the DCA as an amendment to S. 1. *See* 149 Cong. Rec. S8686, at S8692 (daily ed. June 26, 2003) (remarks of Sen. Leahy). Meanwhile, the House was considering parallel legislation, H.R. 1, which also provided a Medicare prescription drug benefit and made similar changes to Hatch-Waxman. *See* Lietzan, *supra* at 311. After the House and Senate passed H.R. 1 and S. 1, respectively, on June 26, 2003, the legislation entered conference for several months while legislators attempted to work out the differences between the bills. H. Rep. No. 108-391 (2003). The conference committee dealt primarily with changes to the prescription drug benefit. *Id.* On November 21, 2003, a conference report emerged containing a revised H.R. 1 that was approved by the House and Senate, respectively, on November 22 and 25, 2003. Lietzan, *supra* at 311. The MMA became law on December 8, 2003. MMA, Pub. L. No. 108–173 (December 8, 2003).

271, 355, 355a (2012)). They include: (1) the requirement that manufacturers produce all exclusion-payment agreements to the FTC and DOJ, MMA §§ 1111–1118, 21 U.S.C. § 355 note (2012)[13]; (2) a limitation of one 30-month stay per brand drug, MMA § 1101, 21 U.S.C. § 355(j)(5)(B)(iii) (2012); and provisions designed to allow subsequent generic challengers to trigger the first-filer's 180-day exclusivity if he

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[13] Specifically, three types of agreements are required to be submitted to the FTC and DOJ: (1) an agreement between a generic manufacturer that has submitted an ANDA with a Paragraph IV certification and a brand manufacturer that pertains to: (a) the manufacture, marketing or sale of the pioneer drug; (b) the manufacture, marketing or sale of the generic drug; or (c) any generic manufacturer's 180-day exclusivity with respect to the pioneer drug, MMA § 1112(a)(2); (2) an agreement between two generic manufacturers that have both submitted ANDAs with Paragraph IV certifications to the same listed drug that pertains to one manufacturer's 180-day exclusivity period, MMA § 1112(b); and (3) any agreements not described above that "and are contingent upon, provide a contingent condition for or are otherwise related to an agreement" that is described above, MMA § 1112(c)(2). Manufacturers are required to file any such agreements within ten business days after their execution, subject to civil penalties for failure to do so.

attempts to "park" it, MMA § 1102; 21 U.S.C. § 355(j)(5)(D) (2012).[14]

The FTC enforcement actions, the early condemnation by district courts in private actions, and Congress' swift action brought exclusion payments to a halt beginning in 2000 (temporarily, as it turned out). *See, e.g.*, 148 Cong. Rec. S7342, at S7348 (daily ed. July 25, 2002) (remarks of Sen. Hatch) ("Probably in no small part due to the FTC's vigorous enforcement under the existing antitrust laws and the development of Senator Leahy's Bill [the DCA], I understand that no more of these type of anti-

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[14] The first Paragraph IV ANDA applicant forfeits 180-day exclusivity if it fails to market the drug by the later of: (1) 75 days after the ANDA is approved, or 30 months after the ANDA is filed, whichever is earlier, 21 U.S.C. § 355(j)(5)(D)(i)(I)(aa); or (2) 75 days after one of the following has occurred: (i) a court enters a decision, from which no appeal has been or can be taken, that finds the patent is invalid or not infringed; (ii) a settlement agreement is approved that includes a finding that the patent is invalid or not infringed; or (iii) the patentee withdraws the patent information from the Orange Book, 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb). The MMA also created five additional forfeiture events. *See* 21 U.S.C. § 355(j)(5)(D)(i)(II), (III), (IV), (V) & (VI). Since 2003, brand and first-filing generic manufacturers have skirted the failure-to-market provisions and kept 180-day exclusivity bottlenecks in place by settling their litigation before final judgment and not including a finding of invalidity or non-infringement in the consent judgment. In order to trigger a forfeiture and gain access to the market, subsequent ANDA applicants are then forced to obtain a judgment that all patents for which the first-filer made a Paragraph IV certification are invalid or not infringed. This may require the subsequent ANDA applicant to initiate a declaratory judgment action concerning patents that the brand manufacturer did not assert against it in a patent infringement case.

competitive agreements have been initiated for the past two years."); FTC Statement, at 133 ("For several years, such agreements essentially stopped."). But the Eleventh Circuit's decision in *Schering*, followed by the Second Circuit's decision in *Tamoxifen*, overturned the antitrust law on which Congress' 2003 remedial legislation had been predicated.[15] In

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[15] The Eleventh Circuit's decision in *Valley Drug*, with its ambiguous treatment of exclusion payments, was rendered in November 2003. The provisions amending Hatch-Waxman that became Title XI of the MMA changed only slightly between June 27, 2003, when they passed the House and Senate and went to conference, and December 8, 2003 when they were signed into law. The reporting requirements of the DCA were actually strengthened, as the conference report for H.R. 1 adopted the House version's requirement that agreements between generic manufacturers (not just brand and generics) also had to be filed, and adopted the Senate version's requirement that agreements had to be filed with the DOJ as well as the FTC. *See* MMA §1112 (b)–(c); *Examining the Senate and House Versions of the "Greater Access to Affordable Pharmaceuticals Act," Hearing Before the S. Comm. on the Judiciary* 4 (2003); 149 Cong. Rec. S16104 (daily ed. Dec. 9, 2003) (remarks of Sen. Hatch). None of the changes made from June to December altered Congress' intent to stop exclusion payments. *See, e.g.*, 149 Cong. Rec. S15670, at S15746 (daily ed. Nov. 24, 2003) (remarks of Sen. Schumer) (the legislation "ends" the "abuse" of Hatch-Waxman through the use of "collusive agreements. . . and other tactics that allow [the 180-day] provision to act as a bottleneck to generic competition. . . I am very pleased that the conferees preserved these important, pro-consumer cost containment provisions"); 149 Cong. Rec. S16104, at S16105 (daily ed. Dec. 9, 2003) (remarks of Sen. Hatch) (referring to "anticompetitive agreements [that] were entered into between certain pioneer and generic drug firms[,]" and lauding inclusion in the signed MMA provisions of the DCA "which [are] designed to increase enforcement of longstanding provisions of antitrust

the latest reporting period, the FTC found a record number of potential exclusion payment agreements. *See* FTC, *Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act 2 (FY 2012)*, *available at* http://ftc.gov/os/2013/01/130117mmareport.pdf. In short, by 2010 "the *Schering*, *Tamoxifen*, and *Ciprofloxacin* decisions ha[d] essentially nullified antitrust" by permitting the very agreements the 2003 amendments were designed to curtail. *See* S. Rep. No. 111-123, at 4 n.16 (2010).

Since *Schering* and *Tamoxifen*, the manufacturers have argued to Congress, successfully, that additional remedial legislation is inappropriate because the courts are best positioned to determine whether exclusion payments are anticompetitive. *See, e.g.*, *Paying Off Generics to Prevent Competition with Brand Name Drugs: Should It Be Prohibited?: Hearing on S. 316 Before the Comm. on the Judiciary*, 110th Cong. 77 (2007) (responses of PhRMA president Billy Tauzin to questions submitted) ("[E]ach patent settlement should be evaluated individually to determine whether it is likely to harm competition and consumers. ... [A]ntitrust law already provides a methodology for federal courts and antitrust agencies to distinguish between good and bad patent settlements. This kind of analysis can and should be done under existing antitrust standards...."); *H.R. 1706, The Protecting Consumer Access to Generic Drugs Act of 2009: Hearing on H.R. 1706 Before the*

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law that prevent anti-consumer agreements [referring to FTC's Hytrin and Cardizem cases]").

Subcomm. on Commerce, Trade, and Consumer Protection of the H. Comm. on Energy and Commerce, 111th Cong. 195 (2009) (statement of Diane Bieri) ("[E]nforcement agencies and courts should continue to evaluate settlements on a case-by-case basis to determine whether on the whole they benefit consumers."); *Pay To Delay, Are Patent Settlements That Delay Generic Drug Market Entry Anti-Competitive?: Hearing on S. 369 Before the Subcomm. on Courts and Competition Policy of the H. Comm. on the Judiciary*, 111 Cong. 174 (2009) (remarks of Guy Donatiello) ("[I]t is [already] illegal to settle in violation of the antitrust laws.").[16] NACDS agrees that determining the proper standard for adjudicating whether a business practice unreasonably restrains competition under the Sherman Act is a quintessential function of this Court.

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[16] Post-2003, Congress has considered three types of legislative fixes: (1) declaring any settlement either presumptively or per se anticompetitive if the generic "receives anything of value and . . . agrees to limit or forgo research, development, manufacturing, marketing or sales of the [generic] product for any period of time," Preserve Access to Affordable Generics Act, S. 3582, 109 Cong. (2006), reintroduced as S. 316, 110th Cong. (2007); S. 369, 111th Cong. (2009); and S. 27, 112th Cong. § 3(a) (2011); (2) diminishing the economic incentive for exclusion payments by withholding eligibility for 180-day exclusivity from any generic manufacturer that accepts such payments, Fair and Immediate Release of Generic Drugs Act, S. 1882, 112th Cong. §§ 2 & 3 (2011); and (3) outlawing all exclusion payments except those exempted by the FTC through rulemaking, Protecting Consumer Access to Generic Drugs Act, H.R. 1902, 110th Cong. (2007), reintroduced as H.R. 1706, 111th Cong. (2009), and H.R. 3995, 112th Cong. § 3 (2012).

CONCLUSION

For the reasons stated above, the Court should hold, consistent with the conclusion of the Third Circuit, that an antitrust plaintiff makes a prima facie case of liability by proving that the brand manufacturer made a payment to a generic manufacturer that agreed to restrict entry into the market.

Respectfully submitted.

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APPENDIX

APPENDIX

Act	Bill Number	Major Report	Major Debate	Major Hearing
Hatch-Waxman Legislative History				
Patent Term Restoration Act	H.R. 7952, 96th Cong. (1980) (unenacted)			
	S. 2892, 96th Cong. (1980) (unenacted)		126 Cong. Rec. S 8685 (daily ed. June 27, 1980)	
	H.R. 1937, 97th Cong. (1981) (unenacted)		127 Cong. Rec. E545 (daily ed. Feb. 18, 1981) 127 Cong. Rec. E577 (daily ed. Feb. 19, 1981)	

Appendix

Act	Bill Number	Major Report	Major Debate	Major Hearing
Patent Term Restoration Act (cont.)	S. 255, 97th Cong. (1981) (unenacted)	S. Rep. No. 97-138 (1981)	127 Cong. Rec. S674 (daily ed. Jan. 27, 1981) 127 Cong. Rec. S 4170 (daily ed. April 29, 1981) 127 Cong. Rec. S7542 (daily ed. July 13, 1981) 127 Cong. Rec. S 7354 (daily ed. July 9, 1981) 127 Cong. Rec. S11329 (daily ed. Oct. 7, 1981)	*Patent Term Restoration Act of 1981—S. 255: Hearing Before the S. Comm. on the Judiciary*, 97th Cong. (1981)

Appendix

Act	Bill Number	Major Report	Major Debate	Major Hearing
Patent Term Restoration Act (cont.)	H.R. 6444, 97th Cong. (1982) (unenacted)	H.R. Rep. No. 97-696 (1982)	128 Cong. Rec. E3771 (daily ed. August 10, 1982) 128 Cong. Rec. E4158 (daily ed. Sept. 14, 1982) 128 Cong. Rec. E4159 (daily ed. Sept. 15, 1982) 128 Cong. Rec. E4194 (daily ed. Sept. 15, 1982) 128 Cong. Rec. E4184 (daily ed. Sept. 15, 1982)	*Patent Term Restoration Act of 1982: Hearing Before the Subcomm. on Courts, Civil Liberties, and the Administration of Justice of the H. Comm. on the Judiciary*, 97th Cong. (1981)

Appendix

Act	Bill Number	Major Report	Major Debate	Major Hearing
Patent Term Restoration Act (cont.)	H.R. 6444, 97th Cong. (1982) (unenacted) (cont.)		128 Cong. Rec. E4205 (daily ed. Sept. 15, 1982) 128 Cong. Rec. H6982 (daily ed. Sept. 15, 1982) 128 Cong. Rec. H6983 (daily ed. Sept. 15, 1982) 128 Cong. Rec. H6983 (daily ed. Sept. 15, 1982) 128 Cong. Rec. H7158 (daily ed. Sept. 16, 1982)	
	H.R. 3502, 98th Cong. (1983) (unenacted)			

Appendix

Act	Bill Number	Major Report	Major Debate	Major Hearing
Patent Term Restoration Act (cont.)	S. 1306, 98th Cong. (1983) (unenacted)		129 Cong. Rec. S6863 (daily ed. May 17, 1983) 129 Cong. Rec. E3316 (daily ed. June 30, 1983) 129 Cong. Rec. E3384 (daily ed. July 11, 1983) 129 Cong. Rec. E3459 (daily ed. July 13, 1983) 129 Cong. Rec. S10773 (daily ed. July 25, 1983) 129 Cong. Rec. S16729 (daily ed. Nov. 17, 1983)	*The Patent Term Restoration Act of 1983: Hearing Before the Subcomm. on Patents, Copyrights and Trademarks of the S. Comm. on the Judiciary*, 98th Cong. (1983)

Appendix

Act	Bill Number	Major Report	Major Debate	Major Hearing
Patent Law Amendments of 1983	H.R. 2610, 98th Cong. (1983) (unenacted)		129 Cong. Rec. H2187 (daily ed. April 19, 1983)	
Drug Price Competition and Patent Term Restoration Act	S. 1538, 98th Cong. (1983) Pub. L. No. 98-417 S. Con. Res. 141, 98th Cong. (1984)	S. Rep. No. 98-547 (1984)	129 Cong. Rec. S9009 (daily ed. June 23, 1983) 130 Cong. Rec. S10981 (daily ed. Sept. 12, 1984) 130 Cong. Rec. S11096 (daily ed. Sept. 12, 1984) 130 Cong. Rec. H9547 (daily ed. Sept. 14, 1984)	*The Patent Law Amendments Act of 1983: Before the Subcomm. on Patents, Copyrights and Trademarks of the S. Comm. on the Judiciary*, 98th Cong. (1983)

Appendix

Act	Bill Number	Major Report	Major Debate	Major Hearing
Drug Price Competition and Patent Term Restoration Act (cont.)	H.R. 3605, 98th Cong. (1984) (incorporated into S. 1538)	H.R. Rep. No. 98-857, pt. 1 & 2 (1984)	130 Cong. Rec. E3621 (daily ed. August 10, 1984) 130 Cong. Rec. E3840 (daily ed. Sept. 13, 1984) 130 Cong. Rec. E3843 (daily ed. Sept. 13, 1984) 130 Cong. Rec. H9105 (daily ed. Sept. 6, 1984) 129 Cong. Rec. E3581 (daily ed. July 19, 1983) 130 Cong. Rec. E3621 (daily ed. August 10, 1984)	*Innovation and Patent Law Reform: Hearing Before the Subcomm. on Courts, Civil Liberties, and the Administration of Justice of the Comm. on the Judiciary*, 98th Cong. (1984)

Appendix

Act	Bill Number	Major Report	Major Debate	Major Hearing
Drug Price Competition and Patent Term Restoration Act (cont.)	H.R. 3605, 98th Cong. (1984) (incorporated into S. 1538) (cont.)			*Drug Legislation: Hearing Before the Subcomm. on Health and the Environment of the Comm. on Energy and Commerce*, 98th Cong. (1983)
	S. 2926, 98th Cong. (1984) (unenacted)		130 Cong. Rec. S10503 (daily ed. August 10, 1984)	

Appendix

Act	Bill Number	Major Report	Major Debate	Major Hearing
Drug Price Competition and Patent Term Restoration Act (cont.)	S. 2748, 98th Cong. (1984) (unenacted)			*Drug Price Competition and Patent Term Restoration Act of 1984: Hearing Before the S. Comm. on Labor and Human Resources*, 98th Cong. (1984)
MMA Legislative History				
Drug Competition Act	S. 2993, 106th Cong. (2000) (unenacted)		146 Cong. Rec. S7908 (daily ed. July 27, 2000)	
	H.R. 5313, 106th Cong. (2000) (unenacted)		146 Cong. Rec. E1538 (daily ed. Sept. 20, 2000)	

Appendix

Act	Bill Number	Major Report	Major Debate	Major Hearing
Drug Competition Act (cont.)	S. 754, 107th Cong. (2001) (unenacted)	S. Rep. No. 107-167 (2002)	147 Cong. Rec. S3711 (daily ed. Apr. 6, 2001) 148 Cong. Rec. S7460 (daily ed. July 29, 2002) 148 Cong. Rec. S11339 (daily ed. Nov. 18, 2002)	*Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements, Hearing No. 107-21 Before S. Comm. on the Judiciary*, 107th Cong. (2001)

Appendix

Act	Bill Number	Major Report	Major Debate	Major Hearing
Drug Competition Act (cont.)	S. 754, 107th Cong. (2001) (unenacted) (cont.)			*Generic Pharmaceuticals: Marketplace Access and Consumer Issues, Hearing Before S. Comm. on Commerce, Science, and Transp.*, 107th Cong. (2002)

Appendix

Act	Bill Number	Major Report	Major Debate	Major Hearing
Drug Competition Act (cont.)	S. 754, 107th Cong. (2001) (unenacted) (cont.)			*Examining Issues Related to Competition in the Pharmaceutical Marketplace: A Review of the FTC Report, Generic Drug Entry Prior to Patent Expiration Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 107th Cong. (2002)

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Act	Bill Number	Major Report	Major Debate	Major Hearing
Drug Competition Act (cont.)	S. 946, 108th Cong. (2003) (unenacted)		149 Cong. Rec. S5486 (daily ed. Apr. 29, 2003)	*Legislative and Regulatory Responses to the FTC Study on Barriers to Entry in the Pharmaceutical Marketplace Hearing Before the S. Comm. on the Judiciary*, 108th Cong. (2003)

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Act	Bill Number	Major Report	Major Debate	Major Hearing
Drug Competition Act (cont.)	S. 1, 108th Cong. (2003) (unenacted)		149 Cong. Rec. S8323 (daily ed. June 23, 2003); 149 Cong. Rec. S8429 (daily ed. June 24, 2003); 149 Cong. Rec. S8686 (daily ed. June 26, 2003)	*Examining the Senate and House Versions of the "Greater Access to Affordable Pharmaceuticals Act," Hearing No. 108-34 Before the S. Comm. on the Judiciary*, 108th Cong. (2003)

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Act	Bill Number	Major Report	Major Debate	Major Hearing
Drug Competition Act (cont.)	H.R. 1, 108th Cong. (2003), Pub. L. No. 108-173	H. Rep. No. 108-391 (2003)	149 Cong. Rec. S15670 (daily ed. Nov. 24, 2003); 149 Cong. Rec. S15882 (daily ed. Nov. 25, 2002); 149 Cong. Rec. S16104 (daily ed. Dec. 9, 2003)	*Examining the Senate and House Versions of the "Greater Access to Affordable Pharmaceuticals Act," Hearing No. 108-34 Before the Sen. Judiciary Comm.*, 108th Cong. (2003)
Greater Access to Affordable Pharmaceuticals Act	S.3051, 106th Cong. (2000) (unenacted)			

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	S. 1225, 108th Cong. (2003) (unenacted)		149 Cong. Rec. S8686-03 (daily ed. June 26, 2003)	*Legislative and Regulatory Responses to the FTC Study on Barriers to Entry in the Pharmaceutical Marketplace Hearing No. 108-16 Before the S. Comm. on the Judiciary*, 108th Cong.

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Act	Bill Number	Major Report	Major Debate	Major Hearing
Greater Access to Affordable Pharmaceuticals Act (cont.)	H.R. 1, 108th Cong. (2003), Pub. L. No. 108-173	H. Rep. No. 108-391 (2003)	149 Cong. Rec. S15670 (daily ed. Nov. 24, 2003) 149 Cong. Rec. S15882-03 (daily ed. Nov. 25, 2002) 149 Cong. Rec. S16104 (daily ed. Dec. 9, 2003)	*Examining the Senate and House Versions of the "Greater Access to Affordable Pharmaceuticals Act," Hearing No. 108-34 Before the S. Comm. on the Judiciary*, 108th Cong. (2003)

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AMICUS CURIAE BRIEF

No. 12-416

Supreme Court, U.S.
FILED
JAN 29 2013
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

FEDERAL TRADE COMMISSION,

Petitioner,

v.

WATSON PHARMACEUTICALS, INC., *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE STATES OF NEW YORK, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, HAWAII, IDAHO, ILLINOIS, IOWA, KENTUCKY, LOUISIANA, MAINE, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MISSISSIPPI, MISSOURI, NEVADA, NEW HAMPSHIRE, NEW MEXICO, NORTH CAROLINA, NORTH DAKOTA, OHIO, OREGON, PENNSYLVANIA, RHODE ISLAND, SOUTH CAROLINA, SOUTH DAKOTA, TENNESSEE, UTAH, VERMONT, WASHINGTON, AND WYOMING, THE DISTRICT OF COLUMBIA, AND THE COMMONWEALTH OF PUERTO RICO AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Federal competition law generally prohibits an incumbent firm from agreeing to pay a potential competitor to stay out of the market. *See Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 49-50 (1990) (per curiam). This case concerns agreements between (1) the manufacturer of a brand-name drug on which the manufacturer assertedly holds a patent, and (2) potential generic competitors who, in response to patent-infringement litigation brought against them by the manufacturer, defended on the grounds that their products would not infringe the patent and that the patent was invalid. The patent litigation culminated in a settlement through which the seller of the brand-name drug agreed to pay its would-be generic competitors tens of millions of dollars annually, and those competitors agreed not to sell competing generic drugs for a number of years. Settlements containing that combination of terms are commonly known as "reverse payment" agreements. The question presented is as follows:

Whether reverse-payment agreements are per se lawful unless the underlying patent litigation was a sham or the patent was obtained by fraud (as the court below held) or instead are presumptively anticompetitive and unlawful (as the Third Circuit has held).

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INTEREST OF THE *AMICI*

Amici are the States of New York, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Hawaii, Idaho, Illinois, Iowa, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nevada, New Hampshire, New Mexico, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Washington, and Wyoming, the District of Columbia, and the Commonwealth of Puerto Rico.[1] The *amici* States have strong interests, both as pharmaceutical purchasers and as antitrust enforcers, in protecting fair competition in pharmaceutical markets.

Prescription drugs represent a major expenditure for the States. States purchase drugs and make reimbursements for the cost of drugs through state Medicaid and other public health programs and agencies.[2] Altogether, state and local health care programs across the country (including Medicaid and the Children's Health Insurance Program) spent approximately $8.6 billion for prescription drugs in 2011.[3] States also have a recognized

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[1]The District of Columbia and the Commonwealth of Puerto Rico are not States, but possess a strong interest in this matter similar to those of the States. They are included in this brief's references to "*amici* States."

[2]The word "purchase" is sometimes used in this brief to include both the direct exchange of money for drugs and the reimbursement of purchases made by others.

[3]*See* U.S. Dep't of Health & Hum. Svcs., *National Health Expenditure Accounts: Methodology Paper, 2011*, at 4 ("Exhibit 1: National Health Expenditures by Type of Expenditure and Program: Calendar Year 2011"), http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/dsm-11.pdf.

interest in enforcing federal antitrust laws to protect their citizens' economic well-being against anticompetitive practices. Citizens of the States spend significant sums on prescription drugs; private and public expenditures for drugs nationwide total more than $260 billion annually.[4] In New York alone, private and public purchasers, including the State's Medicaid program, spent about $19 billion on prescription drugs in 2011.[5]

This case concerns "pay-for-delay" drug patent settlements—agreements that purport to settle drug patent disputes, under which patent holders pay money to potential generic competitors, and the potential competitors agree to delay their entry into the relevant markets. A dispute over the validity or scope of a patent may be appropriately compromised by an agreement that the competitor will enter the market on a negotiated date before the full term of the patent expires. But when a settlement agreement specifying an agreed entry date also includes a payment from the brand-name manufacturer to the potential generic competitor, that payment ordinarily represents an unlawful inducement to the generic to agree to delay entry into the market for a longer period than is warranted by the parties' evaluation of the patent's merits.

The *amici* States have a strong interest in vindicating the Federal Trade Commission's position that pay-for-delay agreements presumptively violate the federal

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[4] *See id.*

[5] Kaiser Family Foundation, *Total Retail Sales for Prescription Drugs Filled at Pharmacies, 2011*, http://www.statehealthfacts.org/comparemaptable.jsp?typ=4&ind=266&cat=5&sub=66&sortc=1&o=a.

antitrust laws. These agreements suppress competition in the pharmaceutical markets by delaying generic entry, and thereby cause direct and substantial economic harm to the States and their residents by increasing drug prices and restricting consumer choice. A recent study shows that "pay-for-delay" agreements cause drug purchasers nationwide to pay $3.5 billion per year more than they would pay if drug litigation settlements did not include pay-for-delay provisions. As major drug purchasers, the *amici* States have a strong interest in avoiding those additional costs, and have standing to sue to protect their proprietary interests. *See, e.g., Massachusetts v. E.P.A.*, 549 U.S. 497, 519 (2007). The States also have statutory standing under the Sherman Act to protect their interest in the economic well-being of their residents. *See* 15 U.S.C. § 15c; *Georgia v. Pennsylvania R.R.*, 324 U.S. 439, 447 (1945); *California v. American Stores Co.*, 495 U.S. 271 (1990).[6] Acting as antitrust enforcers, the States have challenged pay-for-delay agreements to protect their consumers from the artificially high drug prices those agreements make possible. *See, e.g., New York v. Aventis S.A.*, No. 01 Civ. 71835 (E.D. Mich. 2001); *Florida v. Abbott Labs.*, No 01 Civ. 4006 (S.D. Fla. 2002).

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[6]The FTC's claims in this case were brought under the Federal Trade Commission Act, 15 U.S.C. § 45(a); other challenges to similar settlements have been brought under the Sherman Act, 15 U.S.C. § 1. *See, e.g., In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012), *petition for cert. pending*. The court below decided the case on the assumption that the relevant standards are the same under the FTC Act and the Sherman Act. *See* Pet. App. 17a n.5. *Accord FTC v. Motion Picture Adver. Servs. Co., Inc.*, 344 U.S. 392, 395 (1953); *Polygram Holding, Inc. v. FTC*, 416 F.3d 29, 32 (D.C. Cir. 2005). Thus, the States have an interest in the question presented here.

STATEMENT

In this antitrust enforcement action, the Federal Trade Commission alleges that the defendants violated federal antitrust law by settling a patent dispute with agreements under which the manufacturer of a brand-name drug, Solvay Pharmaceuticals, paid money to would-be generic competitors, Watson Pharmaceuticals, Paddock Laboratories, and Par Pharmaceutical Companies, to induce them to delay their entry into the market.[7]

Solvay manufactures and markets AndroGel, a gel formulation of synthetic testosterone that is used to treat low testosterone. (J.A. 36 ¶ 31.) Solvay holds a patent for AndroGel; at the time of the settlement agreements at issue, the patent was scheduled to expire in 2020.[8] (*Id.* at 39 ¶ 43.) Solvay's patent does not cover the drug's active ingredient: testosterone was first synthesized in 1935 and lost patent protection decades ago. (Pet. App. 10a.) Rather, Solvay's patent relates to a particular gel formulation of the drug. (Pet. App. 10a.)

In 2003, Watson and Paddock separately announced plans to market generic testosterone products that would compete with AndroGel. (Pet. App. 10a-11a.) They applied to the Food and Drug Administration (FDA) for approval of their generic products, seeking to take advantage of an abbreviated approval process created by the Drug

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[7]The State of California originally brought this suit jointly with the FTC in federal court in California, but dismissed its claims after the suit was transferred to Georgia over its jurisdictional objections.

[8]The patent was later extended to February 2021. (J.A. 39 ¶ 43.)

Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (the "Hatch-Waxman Act"), for a generic competitor that certifies that its proposed drug is "bioequivalent" to a brand-name drug. 21 U.S.C. § 355(j)(2)(A), (8)(B). In addition to certifying that their proposed drugs were bioequivalent to AndroGel, the generics further certified that AndroGel's patent was invalid or not infringed by their products. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). As to Watson, the first filer, this certification triggered a provision of the Hatch-Waxman Act making the first generic challenger to a brand-name patent potentially eligible for a special 180-day period of exclusivity during which the FDA may not approve other generic versions of the same drug. 21 U.S.C. § 355(j)(5)(B)(iv).

Soon after Watson and Paddock submitted their applications for approval to the FDA, Solvay sued them for patent infringement and, by doing so, obtained an automatic delay in FDA approval of their applications under another provision of Hatch-Waxman. (Pet. App. 11a.)[9] The generics responded to the suit by asserting that their drugs did not infringe Solvay's patent, and that the patent was invalid in any event. (*See* Pet. App. 12a.)

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[9]Under the Hatch-Waxman Act, the FDA's approval of the proposed generic drug product must be delayed for thirty months if a patent-holder brings suit within forty-five days of receiving notice that a generic challenger has certified that it seeks approval of its generic product on the grounds that the brand's patent is invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iii). This period may be adjusted by the court if "either party to the action fail[s] to reasonably cooperate in expediting the action," or if the litigation ends with a judgment of the patent's invalidity or noninfringement. *Id.*

In 2006, the parties settled the case. Watson and Paddock agreed to delay their entry until 2015, five years before the patent was scheduled to expire in 2020 (Pet. App. 10a), by which time Solvay intended to switch its marketing focus to a substitute testosterone product anyway. (J.A. 45 ¶¶ 62-63.) In exchange for this delay, Solvay agreed to pay Watson between $19 and $30 million annually, depending on Solvay's AndroGel profits for the year, and to pay Paddock and Par $10 million per year for six years, plus an additional $2 million. (Pet. App. 12a-13a.) The settlement documents portrayed these payments as compensation for manufacturing or marketing services provided by Watson and Paddock to Solvay. But Solvay had no need for manufacturing or marketing services from its would-be competitors and did not expect to use them, as confirmed by Solvay's own internal analysis, which found that the services had little or no value to the company. (J.A. 44-53 ¶¶ 60-85.)

The FTC filed suit, asserting that the agreements unlawfully extended Solvay's monopoly on AndroGel—not through the strength of its patent but through the financial incentives it offered its competitors. (*Id.* at 61 ¶ 111.) The complaint specifically alleged that the payments to the generics made economic sense only as a mechanism for delaying the generics' competition with Solvay. (*Id.* at 50-53 ¶¶ 81-85.) The complaint also alleged that Solvay was unlikely to have succeeded in its patent suit to exclude the generic competition. (*Id.* at 53-55 ¶¶ 86-92.)

The district court dismissed the FTC's complaint for failure to state a claim (Pet. App. 37a), holding that there was no antitrust violation because the settlement agreements excluded only competition that could already

have been excluded by the patent itself—if the patent were determined valid and the competing generic products were held to infringe it. (Pet. App. 47a-52a.) The United States Court of Appeals for the Eleventh Circuit affirmed (Pet. App. 1a), holding that in the absence of sham litigation or fraud, a settlement of drug patent litigation does not violate antitrust law as long as "its anticompetitive effects fall within the scope of the exclusionary potential of the patent." (Pet. App. 28a.)

SUMMARY OF ARGUMENT

It serves neither the public interest nor the fundamental goals of antitrust law and patent law when brand-name drug manufacturers are allowed to immunize their patents from scrutiny by buying off their potential generic competitors with a share of their monopoly profits, thereby maintaining artificially high drug prices and restricting drug purchasers' choices. Drug patent settlement agreements under which a brand-name manufacturer extends financial consideration to a generic challenger, and the challenger agrees to delay entry into the market, carry an overwhelming tendency to perpetuate monopolies improperly, beyond any point justified by the strength of the patents held by the brand-name manufacturers.

Consequently, this Court should adopt a presumption that pay-for-delay drug patent settlements are anticompetitive and unlawful. Such a settlement should be treated as an unreasonable restraint of trade, unless the settling parties can show that the agreement has procompetitive benefits or that the payment does not represent an inducement to delay entry. *See In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012), *petitions*

for cert. filed, 81 U.S.L.W. 3090 (Aug. 24, 2012) (No. 12-245); 81 U.S.L.W. 3090 (Aug. 29, 2012) (No. 12-265).[10] This approach serves basic principles of antitrust law and patent law, and it promotes the public's especially strong interest in seeing that the validity and scope of pharmaceutical patents are tested, as reflected in the Hatch-Waxman Act. Applying a presumption of illegality also accords with the realities of drug patent practice, because pay-for-delay agreements are usually anticompetitive, and the presumption appropriately permits the parties to those agreements to rebut that conclusion in those limited cases where it may be untrue.

By contrast, the approach adopted by the Eleventh Circuit below would disable antitrust law from policing these drug patent settlements and would permit brand-name drug manufacturers systematically to extend their monopolies, all the way up to patent expiration dates, whenever doing so would enable them to earn more in surplus monopoly profits than they would have to pay competitors to induce them to stay out of the market. The court below held that pay-for-delay agreements are immune from antitrust scrutiny so long as they do not exclude competition beyond "the scope of the exclusionary potential of the patent." (Pet. App. 28a.)[11] This approach,

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[10]The Sixth and D.C. Circuits have also concluded that pay-for-delay settlements raise serious antitrust concerns. *See In re Cardizem CD Antitrust Litigation*, 332 F.3d 896, 908 (6th Cir. 2003); *Andrx Pharmaceuticals v. Biovail Corp. Int'l*, 256 F.3d 799, 806-815 (D.C. Cir. 2001).

[11]*See also In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006). *But see Arkansas*

which has become known as the "scope of the patent" test, would allow brand-name drug manufacturers to exclude competition up to the extent allowed by the patent on its face, even though the questions whether the patent is valid and whether it is infringed remain unresolved. This rule would allow brand-name drug makers to maintain a monopoly, not by virtue of a defensible legal right to exclude competition, but simply by paying generic competitors a share of their monopoly profits. The resulting restraint on competition would come at enormous cost to drug purchasers and the public at large. The Court accordingly should reject the "scope of the patent" test and ensure that pay-for-delay settlements of drug patent disputes are subject to meaningful antitrust scrutiny.

ARGUMENT

I. Pay-for-delay settlements contravene basic principles of antitrust law and patent law.

The issue presented by pay-for-delay drug settlements involves the relationship between two bodies of law—antitrust law and patent law—each of which exists to protect the public good, and each of which is fundamentally undermined by pay-for-delay drug settlements. Consequently, such settlements should be given serious antitrust scrutiny. This scrutiny will promote the objectives of patent law and not—as the court of appeals held—disserve them.

Carpenters Health and Welfare Fund v. Bayer AG, 604 F.3d 98 (2d Cir. 2010) (per curiam) (expressing serious concerns about the "scope of the patent" approach); *rehearing en banc denied*, 625 F.3d 779 (2d Cir. 2010) (Pooler, J., dissenting); *cert. denied*, 31 S. Ct. 1606 (2011).

A. Antitrust law protects the public from anti-competitive practices. One classic form of antitrust violation occurs when one firm preserves a profitable monopoly by paying potential competitors to stay out of the market. *See Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 49-50 (1990). The law forbids this practice because it will often be in a monopolist's economic interests to pay a competitor to stay out of the market. Monopolists are typically able to earn surplus monopoly profits at the public's expense by keeping prices artificially high and restricting output. These surplus profits available to the monopolist usually exceed the combined profits that multiple firms would be able to earn in a competitive market. For this reason, settled law holds that an agreement in which an incumbent firm splits "monopoly rents" with a would-be competitor to preserve the incumbent's monopoly constitutes a per se antitrust violation. *Id.*

The facts of this case—as alleged in the amended complaint and accepted as true on the motion to dismiss—illustrate the way that pay-for-delay settlements of drug patent litigation present just this classic antitrust problem. The FTC's complaint alleges that payments under the settlement agreements from Solvay to its potential generic competitors made economic sense only as a mechanism for delaying the generics' competition with Solvay. (J.A. 50-53 ¶¶ 81-85.) And it alleges that Solvay understood and intended this result. The company sought to preserve its AndroGel monopoly until 2015, when it planned to shift its marketing focus to a substitute testosterone product.

An internal analysis by Solvay, known as "Project Tulip," concluded that it was worth a substantial payment to keep the generic competition out of the market until 2015—that the expected profits during that period from

Solvay's sales of AndroGel at the high prices made possible by the absence of generic competition would exceed, by far more than the payment, the expected profits from sales at the lower volume and competitive price that would be required if the competitors entered the market sooner. (J.A. 43-44 ¶¶ 57-59.) Solvay also concluded that without such a payment, the parties would settle on an earlier entry date, based solely on their views of the validity of the patent and the likelihood that it was infringed by the generics. (*Id.* at 43-44 ¶¶ 58-60.) Solvay estimated that if its generic competitors entered the market, it would lose $125 million a year in profits. (*Id.* at 41 ¶ 49.) Accordingly, Solvay could expect to earn large surplus profits by making very substantial annual payments to its potential competitors—roughly $30 to 40 million per year—to keep generic equivalents to AndroGel off the market. (*Id.* at 46 ¶ 66, 49 ¶ 77.)

The agreements here were thus a textbook example of a monopoly improperly preserved through anticompetitive payments, at the public's expense. Indeed, Solvay agreed to pay one of its competitors, Watson, a percentage of its profits from AndroGel, allowing the competitor to share directly in the surplus profits from the monopoly preserved by the settlement. (*Id.* at 44 ¶¶ 60-61, 46 ¶ 66.) The approach taken by the court below effectively prevents the antitrust laws from regulating such anticompetitive agreements and would permit drug companies, systematically and in case after case, to pay competitors to preserve their monopolies beyond what their patents themselves would allow them to achieve.

B. In addition to violating basic antitrust principles, pay-for-delay settlements of drug patent litigation subvert fundamental principles of patent law. Patent law creates

limited monopolies to encourage innovation for the public good. But it is a basic principle of patent law that the limits on those monopolies must be carefully evaluated and strictly enforced to ensure that competition is restrained only in accordance with the congressional judgments underlying the patent system.

Congress has determined that patents do not reward innovation and do not promote the public interest when they are claimed for products or processes that are not genuinely new, *see* 35 U.S.C. §§ 101, 102 (requirement of novelty); or that can reasonably be derived from existing products or processes, *see id.* § 103 (bar on patentability if subject matter is obvious). *See also id.* §§ 101, 112 (setting forth additional requirements for patentability). Such invalid patents, unless exposed, create improper monopolies that impose higher prices on consumers without conferring any public benefit in return. The same is true when patent holders preserve their monopolies by claiming that patents are infringed by competing products when this is not actually so.

Therefore, this Court has stressed that important public interests are served when the invalidity or limited scope of a patent is revealed: "It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly." *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892). The Court has likewise recognized "the broad public interest in freeing our competitive economy from the trade restraints which might be imposed by price-fixing agreements stemming from narrow or invalid patents." *Edward Katzinger Co. v. Chicago Metallic Manufacturing Co.*, 329 U.S. 394, 400

(1947); *see also Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 100–01 (1993) (noting the "importance to the public at large of resolving questions of patent validity"). These principles would be undermined if brand-name manufacturers were permitted to shield their patents from scrutiny by paying off their challengers with a share of their monopoly rents, and thereby preserve an exclusive market position that may well be unjustified under the patent system.

Allowing drug patents to escape challenge in this way would not only undermine the basic goals of patent law, but also subvert the particularly strong public policy favoring the testing of patents in the pharmaceutical industry, where unwarranted restraints on competition increase the cost of and diminish access to health care. Congress has enacted provisions under the Hatch-Waxman Act specifically to encourage the testing of drug patents through litigation. The Act gives generic manufacturers a significant incentive to challenge weak patents, so that consumers can benefit from lower drug prices when patents are revealed to be invalid or narrower than claimed. *See* S. Rep. No. 107–167, at 4 (2002); H.R. Rep. No. 98–857, pt. 1, at 14, reprinted in 1984 U.S.C.C.A.N. 2647 at 2647.

The Act aims to promote the policy of testing drug patents' strength with several provisions that make litigation more attractive to potential generic competitors. Most importantly, the first generic manufacturer who challenges a brand-name drug's patent receives a valuable benefit: a period of 180 days, beginning when the generic drug is first marketed, during which the FDA will not approve other generic versions of the same drug. 21 U.S.C.

§ 355(j)(5)(B)(iv). Generic challengers also receive the benefit of a streamlined application process for seeking approval of generic equivalents to an existing drug, which is less costly and time-consuming than the ordinary application for approval of a new drug. *See* 21 U.S.C. § 355(j)(2)(A), (8)(B). These incentives are not meant to provide a windfall for generic manufacturers, but rather are created to serve the public interest by facilitating the testing of brand-name drug patents, so that the public can benefit from generic competition if the patent proves to be invalid or to be less expansive than the patent holder claims.

The Hatch-Waxman policy favoring the testing of drug patents is critically important to the States and their residents. Total expenditures on prescription drugs in 2011 were more than $260 billion.[12] The States are major participants in this market, because they expend funds for prescription drugs through Medicaid and other public health programs. In New York, for example, private and public purchasers, including the Medicaid program, spent about $19 billion on prescription drugs in 2011.[13] Altogether, state and local health care programs across the country (including Medicaid and the Children's Health Insurance Program) spent $8.6 billion for prescription drugs in 2011.[14] The average retail price for a brand-name drug in 2007 was $119, while the average price for a generic was about $34, just over one-fourth of the average brand-name price. (J.A. 35 ¶ 28.) When generic competitors successfully challenge a brand-name patent, the benefits

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[12] *See* U.S. Dep't of Health & Hum. Svcs., *supra* note 3, at 4.

[13] *See* Kaiser Family Foundation, *supra* note 5.

[14] *See* U.S. Dep't of Health & Hum. Svcs., *supra* note 3, at 4.

for consumers and governments that participate in the health-care market are substantial, because the availability of a generic substitute for a popular drug has immediate and significant price consequences for drug consumers. A successful challenge to the patent for Prozac, for example, resulted in entry of a generic two and a half years before the patent would have expired, saving consumers about $2.5 billion. (*Id.* at 36 ¶ 30.)

By facilitating the approval of generic drugs and encouraging generics to bring challenges that test the strength of patents on brand-name drugs, Hatch-Waxman has been quite successful overall in increasing the availability of generic drugs. When the statute was passed in 1984, about one-fifth of prescriptions were filled with generic drugs; by 2002, nearly half of all prescriptions were.[15] Before the Act (in 1983), only 35 percent of the top-selling drugs that were no longer under patent had generic versions available; by 1998, nearly all of them did.[16]

But the ability of Hatch-Waxman to serve its objectives is seriously impaired by pay-for-delay settlements. Congress sought to encourage challenges to drug patents

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[15] *See* FTC, Generic Drug Entry Prior To Patent Expiration: An FTC Study at i (2002), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf ("Beyond any doubt, Hatch-Waxman has increased generic drug entry. Generic drugs now comprise more than 47 percent of the prescriptions filled for pharmaceutical products – up from 19 percent in 1984, when Hatch-Waxman was enacted.")

[16] Cong. Budget Office, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry 37 (1998), http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/6xx/doc655/pharm.pdf.

because it understood that the public interest is strongly served when those patents are tested. By contrast, that public interest is undermined when brand-name manufacturers are allowed to immunize their patents from challenge by buying off their competitors with a share of their monopoly profits.

C. The Court should adopt a presumption that drug patent settlements featuring both a payment from the brand-name manufacturer to the generic challenger and a delay in generic entry violate the antitrust laws. Contrary to the view of the court of appeals below, adopting this presumption would not require courts to "min[e] through mountains of evidence" to examine the merits of the underlying patent litigation. (Pet. App. 33a-36a.) A prime virtue of the presumption is that it does *not* require courts to assess whether the terms of the settlement are fair as between the parties or to evaluate the likelihood that the patent would have been upheld if litigated to judgment. If financial consideration from the brand-name manufacturer to the generic competitor is part of a settlement featuring a negotiated entry date, it is reasonable to presume that the generic has agreed to delay entry by some increment in exchange for that additional consideration. The presumption merely acknowledges that the exclusion of competition is the most likely explanation for a Hatch-Waxman settlement having these features. *Cf. California Dental Ass'n v. FTC*, 526 U.S. 756, 770 (1999) (recognizing that a presumption of illegality is appropriate in antitrust cases when "the great likelihood of anticompetitive effects can be easily ascertained" as to a challenged practice). The settling parties may rebut this presumption by showing that the payment is not part of the parties' bargain about the date of generic entry, but

rather addresses some other matter, such as allocation of litigation costs avoided by the settlement, or by proving that the payment serves some procompetitive purpose.

The principle that drug patent disputes should not generally be settled with payments for delay leaves ample room for settling drug patent litigation in ways that are not anticompetitive. For example, no antitrust problem usually arises when the parties to a drug patent dispute resolve the dispute by negotiating a date on which the would-be generic competitor is permitted to enter the market, without a payment from the brand-name drug manufacturer to the generic manufacturer. When such settlements occur without a payment, the interests of the generic manufacturer and the general public are aligned. The generic competitor's incentive is to seek the earliest possible date of entry onto the market, and that is precisely what serves the public interest as well, because it maximizes competition and reduces consumers' costs. Consequently, settlements with agreed entry dates, without a payment for delay, by their nature carry with them public benefits that are similar to those achieved when drug patent disputes are litigated to decision.

Pay-for-delay settlements are a different story, because they allow the brand-name drug manufacturer to purchase more delay in market competition than would result from a negotiation based on the merits of the patent alone. Contrary to the Eleventh Circuit's reasoning (Pet. App. 17a), pay-for-delay settlements do not merely bar competition that is already barred by the patent. The court's position wrongly assumes the validity of the patent. It also assumes that the generic product infringes the patent. But these are the very propositions

that are disputed in the litigation that is the subject of the settlement. By allowing brand-name drug manufacturers to buy exclusion of competition—all the way up to patents' expiration dates if it serves their financial interests—such settlements result in greater monopoly protection than the patents alone could have supported. That result leads to exactly the kind of anticompetitive harm that antitrust law seeks to prevent, and thwarts Congress's policy of promoting challenges to invalid drug patents.

II. Adopting the "scope of the patent" rule would allow brand-name drug manufacturers to exclude competition systematically, unchecked by antitrust law, whenever doing so is profitable.

The court below held that the disguised payments for delay embodied in the AndroGel settlement agreements were permitted as a matter of law, because "the patent holder had a 'lawful right to exclude others' from the market." (Pet. App. 17a, quoting *Valley Drug Co. v. Geneva Pharmaceuticals*, 344 F.3d 1294, 1304 (11th Cir. 2003).) But this begs the question whether the patent holder did in fact have a lawful right to exclude the generic manufacturers. The court of appeals' approach is sometimes described as the "scope of the patent" test, but that label is inaccurate, because the true scope of the patent plays no role in the test. Rather, the test is based solely on the ostensible right to exclude competition asserted on *the face* of the patent, with no acknowledgement that a patent holder's actual right to exclude competition may well be narrower than is asserted on the patent's face or, in the case of an invalid patent, nonexistent. In referring to the patent holder's "lawful right" to exclude others, the Eleventh Circuit assumed that the patent was valid and that the competing

products would have infringed the patent—assumptions that the FTC alleged were incorrect on the facts of this case, and assumptions that are unwarranted as a general rule because challenged patents are frequently found to be invalid or not infringed.

The serious problems that would follow from this Court's adoption of the "scope of the patent" approach are best seen by examining the systematic effects such an approach would have. The "scope of the patent" approach would allow every brand-name drug manufacturer to preserve its monopoly, all the way up to the expiration date on the face of the patent, whenever the monopoly profits it would earn from doing so exceed the amount that would be required to pay the generic competition to stay out of the market. It would not matter whether a brand-name manufacturer's patent was strong or weak. In case after case, the level of drug manufacturers' monopoly profits, rather than the strength of their patents, would determine the degree to which they avoided generic competition. Instead of rewarding innovation, the "scope of the patent" approach would simply reward brand-name drug manufacturers for buying off their competition, and reward generic competitors for agreeing to share in the brand-name manufacturer's monopoly rents.[17]

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[17]The court below mistakenly believed that it would not be profitable for brand-name manufacturers to buy off a generic competitor, because other generic competitors would simply fill the void by bringing their own challenges to the patent. (Pet. App. 35a-36a.) While there may be multiple generic challengers for some drugs, this can hardly be counted on. Once the first challenge has been filed, other generic competitors may not find it profitable to challenge the patent because the valuable 180-day period of exclusivity is available only to the first challenger, and because

This would cause direct harm to the purchasing public through increased prices and restricted choice across the pharmaceutical industry.

A. The systematic consequence of the Eleventh Circuit's rule is to deprive the public of the benefits of antitrust protection wherever it is in the economic interest of patent holders to pay off their potential competitors—and the pharmaceutical industry is rife with such situations. The result will be to enable brand-name drug manufacturers to suppress competition for the full duration of disputed patents, despite the fact that many patents are vulnerable to meritorious challenge, and therefore do not represent a right to exclude competition that would withstand legal scrutiny. An FTC study shows that weak patents are widespread in the pharmaceutical sector: generic competitors who challenge drug patents

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subsequent challengers are prevented from entering the market until the first filer has enjoyed the statutory period of exclusivity. Future generic challengers may also be deterred by provisions in pay-for-delay settlements in which the bought-off generic is allowed to market its own drug in the event of a future successful challenge by another generic. (*See* J.A. 46, 49.) Even if there are multiple generic challengers, a brand-name manufacturer may find it profitable to buy them all off. Indeed, a recent report documents a number of cases in which brand companies paid multiple generic challengers to delay competing with a single brand drug. *See* FTC, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2012* at 1 (Jan. 17, 2013), http://www.ftc.gov/os/2013/01/130117mmareport.pdf. Since only the first challenger is eligible for the 180-day exclusivity period, later challengers can be bought off more cheaply—as illustrated here by the fact that Watson, the first filer (J.A. 40 ¶ 45), received significantly more under the settlements than Paddock and Par (Pet. App. 12a-13a).

prevail nearly three-fourths of the time.[18] There is also evidence that patent practices in the drug industry are growing more aggressive and weak patents are becoming more common. *See, e.g.*, C. Scott Hemphill and Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. Empirical Legal Studies 613, 640-43 (2011) (discussing empirical evidence of a rise in weaker patents).

The allegations in this case suggest that Solvay's AndroGel patent may well be an example of a weak patent that does not serve the purposes of patent law or promote the public interest. The patent does not cover the active ingredient in AndroGel, synthetic testosterone, which lost patent protection decades ago. (Pet. App. 10a.) Solvay's AndroGel patent applies to the gel formulation the product uses to deliver synthetic testosterone, and Solvay's generic competitors argued, before they settled the patent litigation, that the gel formulation was an obvious variation on existing methods or formulations and accordingly not patentable. (J.A. 54 ¶ 88.) The competitors also argued that their generic drugs would not infringe Solvay's patent because their drugs contained ingredients the patent did not cover, and contained amounts different from what Solvay had patented. (*Id.*) And the FTC's complaint in this case alleges that if the underlying patent case had been litigated to conclusion, Solvay's patent would likely have been held not to prohibit competition from the generic drugs. (*Id.* at 53-55 ¶¶ 86-92.)

This case is not unusual. Empirical research has demonstrated that challenges to patents are more likely

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[18]FTC, Generic Drug Entry Prior to Patent Expiration 16 (2002), http://www.ftc.gov/os/2002/07/genericdrug study.pdf.

to occur when a patent is legally weak and the case against its validity or infringement is therefore strong. Hemphill and Sampat, *supra*, at 643. For example, drug patents are more likely to be challenged under Hatch-Waxman when they, like the AndroGel patent at issue here, do not cover the active ingredient in a drug, but rather cover its formulation in a particular product or aspects of the way the product delivers the active ingredient. *Id.*

Therefore, drug patents that draw Hatch-Waxman challenges are less likely than unchallenged patents to represent major innovations of the kind that patent law seeks to reward, and are more likely to represent aggressive claims of rights to exclude competition that are legally tenuous. The "scope of the patent" approach fits badly with these realities of drug patent practice, because many of the patents that are the subject of pay-for-delay agreements could not succeed in excluding competition to the full extent that the patents claim on their faces.

Across the range of cases, if these patents are effectively tested in litigation, or if parties settle patent disputes through negotiations over entry date based on the strength of the patents, the public will benefit from substantial generic competition that the patents, on their faces, purport to exclude. By contrast, if brand-name manufacturers were permitted to obtain the maximum exclusion claimed on the faces of their patents by offering unlimited reverse payments to generic challengers, the public should expect to receive little or no real benefit from generic challenges to drug patents. The approach taken below would enable brand-name drug manufacturers in the aggregate to exclude far more generic competition by agreement than their patents themselves could legally exclude.

B. The systematic harms to the public from pay-for-delay drug settlements are already serious and widespread and would become only more so if this Court were to bless the practice. To date, pay-for-delay settlements have existed under a cloud of questionable legality, as shown by the examples of settlements that mask their pay-for-delay nature through use of in-kind exchanges or camouflaged payment arrangements, such as the "services agreements" that were part of the AndroGel settlement here. Despite questions about their lawfulness, pay-for-delay drug settlements have commonly occurred and have caused significant harm to drug purchasers. A 2010 analysis by the FTC found that pay-for-delay settlements cost drug purchasers $3.5 billion annually.[19] Another empirical study conducted in 2009 estimated that pay-for-delay settlements had cost consumers at least $16 billion since 1993. C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Competition*, 109 Colum. L. Rev. 629, 645, 661 & n.130 (2009).

As would be expected, decisions by the courts of appeals immunizing pay-for-delay settlements from antitrust scrutiny have made pay-for-delay drug settlements more popular. *See Arkansas Carpenters*, 604 F.3d at 109 (noting that pay-for-delay settlements have become more common after the *Tamoxifen* decision). A new FTC report finds that out of the 140 final patent settlements filed in fiscal year 2012, forty contained a payment to the generic and a restriction on the generic's ability to market its product, and these forty drugs had

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[19] FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 2 (2010), http://www.ftc.gov/os/2010/01/10011payfordelayrpt.pdf.

combined annual U.S. sales of more than $8.3 billion.[20] The FTC has found that the number of pay-for-delay drug settlements has risen every year since 2004.[21]

A ruling by this Court that adopted the "scope of the patent" test would cause brand-name drug manufacturers to become yet more brazen in their use of reverse payments to exclude competition. That rule would result in the systematic use of untested patents to maintain improper monopolies at serious cost to health-care consumers, even when the patents are invalid or are not infringed by the generic alternative that the settlement keeps off the market. The rule would also encourage drug manufacturers to apply for marginal patents more frequently than they already do, since they could be assured of their ability to insulate those patents from legal scrutiny by paying off potential generic challengers. Antitrust law would be disabled from policing whether brand-name drug manufacturers were preserving monopolies by splitting monopoly rents with their potential generic competitors, rather than by virtue of the strength of their patents.

C. Defenders of pay-for-delay drug settlements sometimes claim that analogous settlements are pervasive outside the Hatch-Waxman context. *See, e.g.*, Br. in Opp. for Solvay Pharms., at 17 (Nov. 13, 2012). However, they

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[20] *See* FTC, *supra* note 17.

[21] *Id.*; *see also* FTC, "FTC Study: In FY 2012, Branded Drug Firms Significantly Increased the Use of Potential Pay-for-Delay Settlements to Keep Generic Competitors off the Market (Press Release, Jan. 17, 2013), http://www.ftc.gov/opa/2013/01/mmarpt.shtm.

have failed to adduce any evidence of such settlements. Instead, they have offered inapt comparisons to another, different kind of patent settlement that they say occurs elsewhere, namely settlements under which a patent holder agrees to forgo some portion of accrued damages claimed for patent infringement, and the alleged infringer accepts an injunction. But the comparison is flawed, because settlements outside the pharmaceutical industry where damages claims are compromised do not present the systematic anticompetitive consequences that pay-for-delay drug settlements do.

In patent disputes outside the Hatch-Waxman context, a patent holder may seek damages for past patent infringement and an injunction to bar ongoing practice of the patented technology. By contrast, Hatch-Waxman patent disputes rarely involve a claim by the patent holder seeking damages for past infringement because the Hatch-Waxman Act affords the brand-name drug manufacturer the ability to block the FDA's approval of the generic's application simply by filing suit within a designated period after the application was filed. 21 U.S.C. § 355(j)(5)(B)(iii). Therefore, in these patent disputes, the generic competitor has not entered the market at the time of suit.

Where damages for infringement are sought outside the Hatch-Waxman context, the fact that a patent holder settles a claim for damages for less than the amount of damages sought in the complaint does not suggest that the patent holder has given any financial inducement for the alleged infringer to agree to greater exclusion from the market than the infringer otherwise would. Plaintiffs typically release claims for damages in exchange for payments lower than the amount of damages sought in

a complaint, due to uncertainty as to whether they will prevail and to what extent, as well as the expenses of litigation. The mere fact that the patent holder settles for less than the amount of damages sought in the complaint thus has no significance; the settlement amount may merely reflect the fair value of the damages claim. A patent holder's agreement to compromise a damages claim in a settlement that also involves a period of exclusion is not suspect from an antitrust perspective, unless the patent holder agrees to settle the damages claim more cheaply than it would if it were the only relief sought in the litigation.

By contrast, when a Hatch-Waxman settlement features a reverse payment from brand-name manufacturer to generic manufacturer, that compensation ordinarily represents an inducement to the generic competitor to delay its entry beyond the date to which the generic would have agreed if negotiations had proceeded solely on the strength of the patent. Economic modeling confirms that as long as the amount of the reverse payment exceeds the patent holder's anticipated future litigation costs, drug patent settlements will generally delay entry beyond what the patent-holders believe they could achieve through negotiation on the basis of the patent's strength. *See* Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, 91 Tex. L. Rev. 283 (2012). Reverse-payment drug patent settlements therefore carry a strong anticompetitive tendency that is not present in settlements where patent holders compromise damages claims for less than the amount claimed in the complaint.

Moreover, though it is theoretically possible that a patent holder could settle its damages claim at a discount to the claim's fair value for the purpose of

inducing a competitor to agree to greater delay in entry, this possibility does not raise the broad potential for systematic exclusion of competition that is created by the pay-for-delay drug settlements at issue here. The amount of the inducement a patent holder can offer by settling its damages claim cheaply is limited by the fair value of the damages claim in the first place. That value is likely to be small in the case of a weak or narrow patent, and therefore the holder of such a patent will have little ability to use a heavily discounted settlement of a damages claim to pay the generic competitor for delay.

By contrast, if pay-for-delay drug settlements featuring reverse payments were immunized from antitrust scrutiny under a "scope of the patent" rule, the brand-name drug manufacturer would have the freedom to pay the generic competitor as much as it would like to pay to obtain additional exclusion, all the way through the expiration date of the patent. A brand-name manufacturer would therefore purchase additional exclusion as long as the manufacturer could earn more in surplus profits by maintaining its monopoly than it would have to pay to induce generic competitors to stay out of the market for the additional period. It would not matter whether the brand-name manufacturer's patent was strong and broad or whether it was weak and narrow. The potential to earn surplus monopoly profits, not the strength of the patent, would determine how much exclusion a brand-name drug manufacturer would obtain in a drug-patent settlement.

This potential for far-reaching and systematic exclusion of competition makes pay-for-delay drug settlements deeply damaging to basic principles of antitrust and patent law. If the "scope of the patent" test were adopted, brand-name manufacturers and generic

competitors would split monopoly rents in case after case, thereby reviving in the pharmaceutical industry a classic form of antitrust problem thought put to rest long ago.[22]

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted,

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Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF OF *AMICUS CURIAE* NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF RESPONDENTS

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BRIEF OF *AMICUS CURIAE* NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF RESPONDENTS

STATEMENT OF INTEREST OF *AMICUS CURIAE*

This brief *amicus curiae* is respectfully submitted on behalf of the New York Intellectual Property Law Association ("NYIPLA" or "Association") in support of respondents.[1]

[1] Pursuant to Sup. Ct. R. 37.6, the NYIPLA and its counsel represent that they have authored the entirety of this brief, and that no person other than the *amicus curiae* or its counsel have made a monetary contribution to the preparation or submission of this brief. Pursuant to Sup. Ct. R. 37.2(a), the written consents to this filing from all parties are submitted herewith.

The arguments in this brief were approved by an absolute majority of the officers and members of the Board of Directors of the NYIPLA, including any officers or directors who did not vote for any reason including recusal, but do not necessarily reflect the views of a majority of the members of the Association, or of the law or corporate firms with which those members are associated. After reasonable investigation, the NYIPLA believes that no officer or director or member of the Amicus Briefs Committee who voted in favor of filing this brief, nor any attorney associated with any such officer, director or committee member in any law or corporate firm, represents a party to this litigation. Some officers, directors, committee members or associated attorneys may represent entities, including other *amici curiae*, which have an interest in other matters that may be affected by the outcome of this litigation.

A. The NYIPLA

The NYIPLA is a professional association of more than 1,300 attorneys whose interests and practices lie in the area of patent, copyright, trademark, trade secret and other intellectual property ("IP") law. The Association is one of the largest regional IP bar associations in the United States. The NYIPLA's members include in-house counsel serving businesses and other organizations that deal with IP rights in all technologies and disciplines, as well as attorneys in private practice who represent both IP owners and their adversaries (many of whom are also IP owners). The entities served by the Association's members include inventors, entrepreneurs, venture capitalists, businesses, universities and industry and trade associations.

Many of the NYIPLA's members represent and counsel their clients as plaintiffs and defendants in patent litigation, including patent infringement litigation arising under the Drug Price Competition and Patent Term Restoration Act of 1984 as amended ("Hatch-Waxman Act").[2] Most notably for purposes of this brief *amicus curiae*, the Association's members represent clients, like Respondents, that are both branded innovator and generic pharmaceutical manufacturers.

B. The NYIPLA's Prior Involvement With These Important Issues

This proceeding represents the ninth time that this Court has been asked to review a decision of a United States court of appeals construing the antitrust legality of a reverse payment term in an agreement settling a patent infringement action brought under the Hatch-Waxman Act,[3] and the first time that such review has been granted. This is the third such proceeding in which the NYIPLA has filed a brief

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[2] Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360(cc) (2000), 35 U.S.C. §§ 156, 271 and 282 (2000), as amended by Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("2003 MMA Amendment"), Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended at 21 U.S.C. § 355(j)(5)(C)(i) (West Supp. 2004) and 35 U.S.C. § 271(e)(5) (West Supp. 2004)). Counseling is also as to 35 U.S.C. §§ 154(a)(1) and 261 (2000).

[3] A "reverse payment term" in a Hatch-Waxman settlement is an undertaking by the branded innovator patentee to transfer one or more cash payments or other consideration to the potential generic seller who infringed the Orange Book patent by filing the Abbreviated New Drug Application ("ANDA") under Paragraph IV. A Hatch-Waxman settlement containing a reverse payment term is a "reverse payment settlement."

amicus curiae, and the first in which it has filed such a brief on the merits.

1. *Andrx v. Kroger*

Nine years ago, the NYIPLA filed a brief *amicus curiae* supporting the grant of certiorari to the generic petitioner seeking review of the Sixth Circuit's *Cardizem* decision,[4] the second of the nine appellate decisions involving a reverse payment settlement that this Court has been asked to review.[5] In *Andrx v. Kroger*, the Association supported the grant of certiorari primarily for the reason that counseling clients who participated in Hatch-Waxman patent litigation by its members had become problematic because of the campaign against reverse payment settlements that the Federal Trade Commission ("FTC" or "Commission") had initiated in 1999.[6]

NYIPLA argued that certiorari should be granted because of what it initially viewed as an irreconcilable conflict between the apparent application of a rule of *per se* illegality by the Sixth Circuit in the *Cardizem* decision and a seemingly antithetical antitrust analysis premised upon a nuanced

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[4] *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003) ("*Cardizem*"), *cert. denied sub nom. Andrx Pharms., Inc. v. Kroger Co.*, 543 U.S. 939 (2004) ("*Andrx v. Kroger*").

[5] "Motion Of New York Intellectual Property Law Association And Brief Of *Amicus Curiae* In Support Of Petitioner in *Andrx v. Kroger*" ("NYIPLA's *Andrx v. Kroger* Brief").

[6] *Id.* at 8-15. The FTC is one of the two federal agencies that are charged with enforcement of the antitrust laws. The other is the Antitrust Division ("ATD") of the Department of Justice ("DOJ").

rule of reason inquiry by the Eleventh Circuit in *Valley Drug*.[7]

Certiorari was denied in *Andrx v. Kroger* after the Solicitor General ("SG"),[8] in response to an order of the Court soliciting the views of the SG ("SVSG order"), opined that *Valley Drug* and *Cardizem* could be harmonized.[9] In the SG's view, *Cardizem* should not be treated as a holding that reverse payment terms were *per se* illegal,[10] but rather as a holding that the settlements set forth two restraints which "extended beyond the legitimate **scope of the patent** claims by reaching non-infringing products and conduct by petitioner that the patent conferred no right to exclude or demand."[11]

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[7] *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), *cert. denied sub nom. Walgreen Co. v. Abbott Labs.*, 543 U.S. 939 (2004) ("*Valley Drug*").

[8] The Office of the Solicitor General ("OSG") is the segment of DOJ assigned to represent the United States before this Court and to file briefs amicus curiae on behalf of the United States in response to SVSG orders of this Court. In July 2009 the ATD, an entirely separate unit of DOJ, announced that it would henceforth support the FTC's theory that Hatch-Waxman reverse payment settlements should be evaluated under a "quick look" standard of presumptive illegality.

[9] "Brief For The United States As Amicus Curiae in *Andrx v. Kroger*" at 3-4, 11-15 ("SG's *Andrx v. Kroger* Brief").

[10] The SG noted that "per se treatment is reserved for conduct that has a predictable and pernicious anticompetitive effect." *Id.* at 7.

[11] *Id.* at 13 (emphasis supplied). Thus, the SG found both (1) that the district court and the FTC's original complaint had characterized the settlement agreement as excluding non-infringing and potentially non-infringing products from the market, and (2) that the agreement prevented Andrx from "relinquishing or otherwise compromising its right to the 180-

Four other aspects of the SG's *Andrx v. Kroger* Brief are worthy of note. First and most importantly, it seems clear that the SG's brief represented the first time that this Court was told authoritatively that (a) the "scope of the patent" standard represented an appropriate threshold adjunct to the rule of reason under which the antitrust legality of Hatch-Waxman reverse payment settlements must be assessed; and (b) the rule of reason should be deemed inherently preferable to any rule of *per se* illegality.[12] Second, the FTC through its General Counsel joined in the SG's arguments, thereby endorsing both the SG's repeated rejections of the application of any rule of *per se* illegality to Hatch-Waxman infringement settlements and his interpretation of the Sixth Circuit's *Cardizem* decision as applying the "scope of the patent" rule.[13] Third, the settlement agreements

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day period of exclusivity," thus creating a bottleneck to any further generic competition. *Id.*

[12] As developed in Section I, the "scope of the patent" threshold standard under the rule of reason actually antedates the 1890 enactment of the Sherman Act. Applied initially to patent-leveraged tying of staple goods and resale price maintenance ("RPM"), rather early in the life of the Sherman Act, the rule was revived for application to price-fixing cartel cases during and after World War II, and resurrected in two important lines of cases decided after the 1982 creation of the Federal Circuit, most notably in *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (Fed. Cir. 1992) ("*Mallinckrodt*") and *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322 (Fed. Cir. 2000) ("*Xerox/ISO*"), *cert. denied sub nom. CSU, L.L.C. v. Xerox Corp.*, 531 U.S. 1143 (2001) ("*CSU v. Xerox*").

[13] Unfortunately, several documents issued thereafter by the FTC staff have ignored this fundamental concession, including the January 2010 FTC Staff Study entitled "Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions" ("2010 Pay-for-Delay Study"), characterizing the *Cardizem* case

in *Cardizem* as construed by the SG are the same agreements construed by the D.C. Circuit in *Biovail*,[14] the first reverse payment case this Court was asked to review via certiorari. Finally, the SG quite candidly explained why the *per se* rule of illegality could not be applied in *Cardizem* by setting forth a catalogue of facts which could tip the balance of the required rule of reason inquiry in favor of a determination that any particular reverse payment settlement would have to be deemed pro-competitive.[15]

The Association believes that it was the first *amicus curiae* ever to demonstrate to this Court, within the context of reverse payment settlements, the pervasive importance of: (1) this Court's prior decision in *PRE*;[16] (2) the decision of the Court of Appeals for the Federal Circuit in *Xerox/ISO*, as well as the SG's comments thereon in *CSU v. Xerox*;[17] and (3) this Court's decision in *Gasoline Cracking*.[18]

2. *Merck v. LWDC*

After the SG had explained how the *Biovail* and *Cardizem* decisions could be harmonized with *Valley*

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as holding that reverse payment settlements "were automatically (or *per se*) illegal."

[14] *Andrx Pharms., Inc. v. Biovail Corp.*, 256 F.3d 799 (D.C. Cir. 2001), *cert. denied*, 235 U.S. 931 (2002) ("*Biovail*").

[15] SG's *Andrx v. Kroger* Brief at 9-10.

[16] *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49 (1993) ("*PRE*").

[17] "Brief for the United States as Amicus Curiae in *CSU v. Xerox*" ("SG's *CSU v. Xerox* Brief").

[18] *Standard Oil Co. (Ind.). v. United States*, 283 U.S. 163 (1931) ("*Gasoline Cracking*"); *see also* NYIPLA's *Andrx v. Kroger* Brief at 4, 6, 8-10, 11-12, 14-15.

Drug and certiorari had been denied in *Andrx v. Kroger*, NYIPLA and its members enjoyed a period of more than eight years during which the "scope of the patent" standard was further developed and universally applied under the rule of reason in no less than five additional reverse payment cases which eventually reached this Court via petition for certiorari, the last of which being the decision below of the Court of Appeals for the Eleventh Circuit in *FTC v. Watson* which issued on April 25, 2012.[19] During that period NYIPLA's members were able to advise their clients reliably regarding the initiation and settlement of Hatch-Waxman infringement suits.[20]

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[19] In chronological order, those cases were *In re Schering-Plough Corp.*, 136 F.T.C. 956 (2003), *vacated, Schering-Plough Corp. v. Fed. Trade Comm'n*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006) ("*Schering-Plough*"); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2nd Cir. 2006), *cert. denied sub nom. Joblove v. Barr Labs., Inc.*, 551 U.S. 1144 (2007) ("*Tamoxifen*"); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed Cir. 2008), *cert. denied sub nom. Ark. Carpenters Health & Welfare Fund, Paper, A.F. of L. v. Bayer AG*, 129 S. Ct. 2828 (2009) ("*Cipro IV*"); *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98 (2d Cir. 2010), *reh'g denied*, 625 F.3d 779 (2d Cir. 2010), *cert. denied sub nom. Louisiana Wholesale Drug Co., Inc. v. Bayer AG*, 131 S. Ct. 1606 (2011) ("*Cipro V*"); *Fed. Trade Comm'n v. Watson Pharms., Inc.*, 677 F.3d 1298 (11th Cir. 2012) ("*FTC v. Watson*"), *cert. granted sub nom. Fed. Trade Comm'n v. Actavis, Inc.*, 133 S. Ct. 787 (U.S. Dec. 7, 2012) (No. 12-416) ("*FTC v. Actavis*"). Citations to the Eleventh Circuit opinion are to Appendix A to the Government's Petition for Certiorari ("Petition") in *FTC v. Actavis* ("PA" 1a-36a).

[20] Since under the rationale of the SG's *Andrx v. Kroger* Brief each of the first seven appellate decisions to reach this Court applied the scope of the patent test, the NYIPLA believed that

On July 16, 2012, however, the Third Circuit issued its decision in *K-Dur*,[21] flatly rejecting the theretofore universally accepted "scope of the patent" threshold standard under the rule of reason as inappropriate for determining the antitrust legality of Hatch-Waxman reverse payment settlements. At the behest of the FTC and the ATD,[22] the Third Circuit panel instead reasoned (1) that it was free to ignore the rule of reason completely and instead employ a "quick look" test to find the agreements presumptively unlawful; and (2) that under *Biovail* and the opinion of the Commission in *Schering-Plough*, it could ignore the need to establish an anticompetitive effect in some properly defined relevant product market by instead presuming that the "quid pro quo" for the reverse payment "was an agreement by the generic to defer entry beyond the date that represents an otherwise logical litigation compromise."[23]

On September 24, 2012, the Association filed with this Court its "Brief Of Amicus Curiae New York Intellectual Property Law Association In Support Of Petitioners" challenging the *K-Dur* decision in *Merck v. LWDC* ("NYIPLA's *Merck v. LWDC* Brief"),

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the conflict it perceived initially was illusory and that certiorari was properly denied by this Court in each of those cases.

[21] *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012) ("*K-Dur*"), *petitions for cert. filed sub nom. Merck & Co. v. Louisiana Wholesale Drug Co.*, (U.S. Aug. 24, 2012) (No. 12-245) and (U.S. Aug. 29, 2012) (No. 12-265) ("*Merck v. LWDC*").

[22] "Brief For The United States As Amicus Curiae Supporting Plaintiffs-Appellants in *K-Dur*" ("ATD's *K-Dur* Brief"); "Brief Of The Federal Trade Commission As *Amicus Curiae* Supporting Appellants And Urging Reversal in *K-Dur*" ("FTC's *K-Dur* Brief").

[23] *K-Dur*, 686 F.3d at 218.

directed to four questions which the Association believed should be answered to provide the proper bases for determining whether the judgment of the Third Circuit panel could be sustained.

INTRODUCTION

A. The Grant Of Certiorari And The Government's Brief On The Merits

On October 4, 2012, shortly after NYIPLA's filing in *Merck v. LWDC*, the OSG filed its petition for certiorari on behalf of the FTC in this proceeding. A significant portion of that petition was devoted to arguments regarding the alleged superiority of *FTC v. Actavis* over *Merck v. LWDC* as a vehicle for determining the proper methodology under which to assess the antitrust legality of reverse payment settlements. Thus, rather than defend the **first** application by any court of appeals of the "quick look" test of presumptive illegality to **any** antitrust case involving a patent,[24] the Government has elected to challenge the **eighth** court of appeals application of the threshold scope of the patent standard under the rule of reason. The Government's petition for certiorari was granted on December 7, 2012. Presumably, the Court intends to maintain jurisdiction over *Merck v. LWDC* until it has decided *FTC v. Actavis*, and then remand the former under an appropriate

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[24] As discussed in Section II, in what NYIPLA believes was the only other patent case in which the FTC ever attempted to convince a court of appeals to employ a "quick look" test of presumptive illegality, that effort was squarely rebuffed in an 8-2 ruling by the Federal Circuit sitting en banc. *Princo Corp. v. Int'l Trade Comm'n*, 616 F.3d 1318 (Fed. Cir. 2010) (en banc) ("*Princo v. ITC*").

grant, vacate and remand ("GVR") order.[25] Despite the Government's election to attack rather than defend, its brief on the merits docketed on January 22, 2013 is sprinkled with references to the Third Circuit's decision in *K-Dur*.[26]

B. The Patent, Parties, ANDAs And Agreements

Pursuant to the admonition against duplicative briefing by *amici* in Sup. Ct. R. 37.1, NYIPLA relies upon and incorporates by reference the statements and appendix references set forth (1) at pages 3-11 of the "Brief For Respondent Actavis, Inc." ("Actavis Brief"); (2) at pages 23-31 of the "Brief For Respondents Par/Paddock" ("Par/Paddock Brief"): and (3) at pages 2-8 of the "Brief For Respondent Solvay Pharmaceuticals, Inc." ("Solvay Brief").[27]

C. The Asymmetrical Economics Of The Hatch-Waxman Act

The *Valley Drug*, *Schering-Plough*, and *Tamoxifen* courts each drew heavily from the legal and economic reasoning of three district court decisions. Thus, *Valley Drug* relied extensively upon *Cipro II*,[28]

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[25] Presumably also, the circumstances regarding the apparent recusal of Justice Alito in *FTC v. Actavis* are such that they extend to *Merck v. LWDC* as well.

[26] The Association respectfully reserves the right to rebut the Government's citations to *K-Dur* with references and arguments directed to the manifest deficiencies of the Third Circuit's reasoning.

[27] Between 2000 and 2007, revenue from the sale of AndroGel in the United States exceeded $1.8 billion. *See* PA 10a.

[28] *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003) ("*Cipro II*").

Schering-Plough upon *Cipro II* and *Asahi Glass*,[29] and *Tamoxifen* upon *Cipro III*[30] and *Asahi Glass*. Each of the three district court decisions emphasized the "asymmetries" in the economics of the litigation and settlement leverage to which the parties are exposed under the Hatch-Waxman Act and cautioned lest overly zealous and unwarranted application of the antitrust laws should undermine the salutary objectives of the Congressional plan.[31]

1. *Patent Strength And "At Risk Entry"*

The agreed date of entry in any Hatch-Waxman settlement will depend upon the parties' respective views of the strength of the patent(s) in suit. This Court should note that the incentives for early challenges to Orange Book patents which Congress provided in the Hatch-Waxman Act are more than counterbalanced by the skewed economic forces which make any prospect of "at risk entry" by a generic so dangerous.[32]

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[29] *Asahi Glass Co. v. Pentach Pharm., Inc.*, 289 F. Supp. 2d 986 (N.D. Ill. 2003) ("*Asahi Glass*").

[30] *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005) ("*Cipro III*").

[31] The two eminent jurists who authored those three opinions had been specifically selected to deal with the complex legal, technical and economic issues involved: the late David G. Trager, D.J. by the Judicial Panel on Multidistrict Litigation, and Richard A. Posner, C.J. sitting by special designation in the Northern District of Illinois.

[32] The term "at risk entry" refers to the market introduction of a generic product after expiration of the automatic stay of FDA approval but before any holding by the court that the patent is invalid or that the approved formulation does not infringe.

If the generic manufacturer should launch "at risk" and lose, the same price reductions which benefit consumers would raise potential damages far beyond the total profits that the generic manufacturer could reasonably expect to earn. There has been no showing that any generic respondent in this action has ever launched at risk. Given the uncertainties of patent litigation stressed by the three early district court decisions and the decision below,[33] it is not unexpected that history has confirmed the economic theory that most generic defendants will not attempt at risk entry.

The reluctance of generic manufacturers to enter the market at risk has been confirmed by a 2010 Royal Bank of Canada study which showed that while 158 Hatch-Waxman patent infringement suits had settled during the seven-year period 2003-2009, only 28 at risk launches had occurred, an average of only four per year.[34] The RBC Study also reported that the all but nine of the at risk launches were attributable to Teva (12), Sandoz (6) and Apotex (1), the three largest generic manufacturers.[35]

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[33] "A party likely to win might not want to play the odds for the same reason that one likely to win a game of Russian roulette might not want to take a turn." PA 30a.

[34] "Pharmaceuticals: Analyzing Litigation Success Rates," RBC Capital Markets Publication (January 15, 2010) ("the RBC study").

[35] Even the largest generic manufacturers can miscalculate, as Apotex found when it was preliminarily enjoined just three weeks after launching its generic Plavix product in 2006 and then had to wait more than six years for the final bill, which totaled more than $500 million untrebled. *See Sanofi-Aventis v. Apotex Inc.*, 748 F. Supp. 2d 293 (S.D.N.Y. 2010).

2. *The Ability To Settle Remains Critically Important For Generics*

The efficient management of litigation resources is critical for a generic manufacturer. The ability to manage the Hatch-Waxman docket efficiently can be the key to the success of a generic firm as each generic manufacturer tries to be the first to challenge the weakest patent with the greatest potential sales.

A large portion of the Hatch-Waxman Act's enormous success probably can be attributed to the subjective and objective assessments of patent strength which invariably are made by the technically sophisticated and well advised litigants who conclude these settlements. The FTC is wrong to suggest that the parties are not better equipped than any potential trier of fact to determine what reasonable agreed entry dates should result from Hatch-Waxman settlements.

That being said, it is equally true that no Hatch-Waxman suit can be settled unless the generic manufacturer will agree upon a date of entry which is acceptable to the patent owner. Indeed, it is impossible to settle any patent infringement suit, including a Hatch-Waxman suit, without the consent of the patent owner. Since the patent owner is permitted to "try its losers" unless the *PRE* standards are satisfied, moreover, the potential generic entrant can often face the prospect of a more protracted and expensive litigation than its initial assessment of the Orange Book patents of its adversary may have indicated.

The Generic Pharmaceutical Association ("GPhA"), the trade association of the generic segment of the pharmaceutical industry, filed a short but compelling

brief opposing rehearing and rehearing en banc after the panel decision in *Tamoxifen*.[36] A substantial portion of the business of every generic manufacturer is devoted to researching and challenging Orange Book patents, and the brief points out that at any one time every such manufacturer may have upwards of a dozen patents in litigation with full knowledge that it cannot afford "to try all of those to final judgment on appeal."[37]

The GPhA *Tamoxifen* Brief also indicates how reverse payment settlements not only permit generic manufacturers to recoup their litigation costs, but also to reallocate funds to other active cases and finance the initiation of additional litigation.

3. *The Hatch-Waxman Legislation Has Proved Enormously Successful*

Due to the Hatch-Waxman Act, the generic pharmaceutical manufacturing business in the United States has expanded exponentially since 1984, has generally become more profitable, and has experienced a high rate of success for the early introduction of generic pharmaceuticals.

Since enactment of the Hatch-Waxman Act, the percentage of United States prescriptions filled by generics has been almost exactly reversed—from 19%

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[36] "Brief Amicus Curiae Of The Generic Pharmaceutical Association In Opposition To Rehearing And Rehearing En Banc in Tamoxifen" ("GPhA *Tamoxifen* Brief"); *see also* "Brief of Amicus Curiae Generic Pharmaceutical Association in Support of Defendants-Appellees and Affirmance in *K-Dur*"; "Brief for Pharmaceutical Research and Manufacturers of America as Amicus Curiae in Support of Appellees in *K-Dur*."

[37] *Id.* at 5.

in 1984 to above 80% in 2011.[38] The annual consumer savings reached almost $200 billion in 2012, and totaled $1.07 trillion over the last ten years.[39] GPhA attributes about one-third of these savings to the ability to settle Hatch-Waxman lawsuits on flexible and pro-competitive terms.[40]

SUMMARY OF ARGUMENT

This case arises at the intersection of patent law, antitrust law, the asymmetrical economics of the Hatch-Waxman Act, and the implications of both (1) the policy objectives of Congress in enacting, amending and refusing to further amend that enormously successful legislation; and (2) the equally important public policy factors favoring the settlement of litigation generally, and patent litigation in particular. Indeed, patent litigation under the Hatch-Waxman Act can be even more protracted and expensive.[41]

Although the issues bearing on the proper disposition of this proceeding are broad and complex, the answers to the Government's arguments are quite

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[38] *See* "The Pharmaceutical Industry, A Discussion of Competitive and Antitrust Issues in an Environment of Change," Bureau of Economics Staff Reports, Federal Trade Commission, March 1999 (19% of scripts were generic in 1984); *see* Generic Drug Pharmaceutical Association, Generic Drug Savings in the U.S. (4th ed. 2012) *Improving Lives for Less* (August 1, 2012) (80% of scripts were generic in 2011) ("*Improving Lives for Less*"); *see also* NYIPLA's *Merck v. LWDC* Brief, Appendices A-D (economic materials).

[39] *See Improving Lives for Less.*

[40] *See id.*

[41] An average investment by the branded patentee of "more than $1.3 billion" and "10-15 years." PA at 2a.

straightforward. NYIPLA's argument will focus on four relatively narrow issues which the parties have touched only lightly if at all.

In Section I we outline the history of the threshold scope of the patent standard under the rule of reason as developed by this Court from its origins at common law and first application to the misuse doctrine almost a century ago. In the Association's view, an understanding of the history of the application of that standard to other areas of the patent-antitrust interface by this Court and, since 1982, by the Court of Appeals for the Federal Circuit, informs the propriety of the application of that threshold standard to reverse payment settlements.

In Section II we contrast the only two "quick look" appellate patent cases and analyze the FTC's success in convincing the Third Circuit to apply a rule of presumptive illegality in *K-Dur* with its complete failure to convince eight of the ten sitting judges of the Federal Circuit to do the same in *Princo v. ITC*. Since the Federal Circuit's reasoning adheres carefully to this Court's precedents, we respectfully submit that its reasoning should be endorsed.

In Section III we employ the SG's arguments regarding *Xerox/ISO*, as made before this Court in response to two separate SVSG orders, to support a broader range of application for *PRE*. The Association respectfully submits that the underlying reasoning of that precedent is so sound and compelling that it should be recognized not only as a definition of the proper scope of the *Noerr-Pennington* immunity, but also as a bright line evidentiary rule of general application at the entire patent-antitrust interface.

Finally, in Section IV we address the FTC's concession (as echoed by the Third Circuit's panel in *K-Dur*) that the rule it asks this Court and Congress to impose upon the industry inevitably would lead to fewer generic challenges to Orange Book patents. Although the Government argues that the risk involved is not great, and that the related cash flow problems the generic manufacturers will encounter if the rule is imposed are beside the point, the Association respectfully submits that any urge to tinker with success must be resisted.

ARGUMENT

I. A NUANCED APPLICATION OF THE THRESHOLD SCOPE OF THE PATENT STANDARD TO REVERSE PAYMENT SETTLEMENTS IS MANDATED BY THIS COURT'S APPLICATION OF EQUITABLE JURISPRUDENCE TO THE PATENT EXEMPTION FOR OVER A CENTURY

If the Government's legal analysis could be taken at face value, this Court would be justified in assuming that the threshold scope of the patent standard under the rule of reason represented some strange and novel approach to the patent-antitrust interface created from whole cloth during the FTC's fifteen-year ongoing crusade against reverse payment settlements. That standard, however, did not simply emerge full-grown from the federal appellate courts after enactment of the Hatch-Waxman Act in 1984, like Athena from the brow of Zeus. To the contrary, the threshold scope of the patent standard had began to develop at common law even before enactment of the Sherman Act in 1890, along with the exhaustion and misuse doctrines, and had been fully articulated

as an adjunct to the equitable defense of misuse by 1917.

A. The Constitutional Predicate For The Patent Exemption

Pursuant to Art. I, Sec. 8, clause 8 of the U.S. Constitution, the first Patent Act was enacted on April 10, 1790, more than a full century before the Sherman Antitrust Act was enacted as the first federal antitrust statute on July 2, 1890.[42] There have been many attempts to encapsulate the relationship between the antitrust and patent laws, perhaps the best and most succinct of them being that of Justice Douglas, in *Simpson v. Union Oil Co.*, 377 U.S. 13, 24 (1964), who found that the patent laws exist "*in pari materia* with the antitrust laws, and modify them *pro tanto*."[43]

Accordingly, antitrust law must yield to the patent laws as properly interpreted. Conduct authorized by the patent laws cannot violate the antitrust laws. Congress can always alter the scope of what is permitted under the patent law to overrule any judicial interpretation of the antitrust laws that it might consider overzealous.[44] Before becoming a

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[42] Brief for Petitioner at Statutory Appendix.

[43] In a real sense, this formulation represented an extremely candid statement of the deference owed to the patent laws. Throughout the almost 37 years of his service on the Court, Justice Douglas consistently championed the interests of economic freedom over those of what he insisted upon calling the "patent monopoly" when considering claims at the patent-antitrust interface.

[44] The 1952 enactment of Sections 271(c) and (d)(1) through (3) of the Patent Act, codified in 35 U.S.C. §§ 271(c) and (d)(1) through (3), represents one good example—intended by Congress to overrule this Court's decisions in *Mercoid Corp. v. Mid-*

threshold adjunct to the antitrust rule of reason, the scope of the patent standard developed along with certain other common law equitable patent defenses which predated the Sherman Act, including the "exhaustion" or "first sale" defense. Since at least 1917, the rule also has represented a useful tool to govern application of the equitable defense of patent misuse, thereby also providing the eventual central doctrinal predicate for delineating the proper balance point as between patent and antitrust.

B. The Early Sherman Act Period

In the early years of the Sherman Act, this Court developed the scope of the patent threshold standard which had originated at common law and applied it (1) to the patent-leveraged tying of staple goods,; and (2) to resale price maintenance ("RPM").

1. *MPP And The Patent Leveraged Tying Of Staple Goods*

This Court announced that the scope of the patent test should be applied to proscribe the patent-based tying of staple goods in *Motion Picture Patents*.[45] Reasoning that "[t]he scope of every patent is limited to the invention described in the claims," the Court held that the language of the statute and rules which define the scope of the patent "is not concerned with,

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Continent Inv. Co., 320 U.S. 661 (1944) ("*Mercoid I*"), and *Mercoid Corp. v. Minneapolis-Honeywell Regulator Co.*, 320 U.S. 680 (1944) ("*Mercoid II*"). *See Dawson Chemical Co. v. Rohm & Haas Co.*, 448 U.S. 176, 188-98 (1980) ("*Dawson*"). Another involves the 1988 enactment of Section 271(d)(5), 35 U.S.C. § 271(d)(5) discussed in *Illinois Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28 (2006) ("*Independent Ink*").

[45] *Motion Picture Patents, Co. v. Universal Film Mfg. Co.*, 243 U.S. 502 (1917) ("*Motion Picture Patents*" or "*MPP*").

and has nothing to do with, the materials with which or on which the machine operates."[46]

Predicated upon that reasoning, the Court overruled[47] *A.B. Dick*,[48] and rejected the philosophy of the *Button-Fastener*.[49]

2. *GE/Lamp, RPM And Manufacturing Licenses*

In *GE/Lamp*,[50] this Court both (1) rejected a claim that General Electric ("GE") had engaged in unlawful resale price maintenance by employing a system of agents who were really wholesale and retail jobbers; and (2) upheld the terms of an agreement under which GE had licensed Westinghouse to manufacture light bulbs under three GE patents and sell those bulbs at prices and terms established by GE—illustrating the significance of this Court's scope of the patent standard.

In *GE/Lamp*, this Court first noted that "under the patent law, the patentee is given by statute a monopoly of making, using and selling the patented article" and concluded that:

> It is only when he adopts a combination with others by which he steps out of the **scope of his patent rights** and seeks to control and restrain those to whom he has sold his patented articles in their subsequent disposition of what is theirs

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[46] *Id.* at 510, 512.

[47] *Id.* at 512.

[48] *Henry v. A.B. Dick Co.*, 224 U.S. 1 (1912) ("*A.B. Dick*").

[49] *Heaton-Peninsular Button-Fastener Co. v. Eureka Specialty Co.*, 77 F. 288 (6th Cir. 1896) ("*Button-Fastener*").

[50] *United States v. General Electric Co.*, 272 U.S. 476 (1926) ("*GE/Lamp*").

> that he comes within the operation of the Anti-Trust Act.[51]

Finding that GE had preserved the formalities of genuine agency and had not made any of the sales for full consideration that would take the price terms outside the scope of the patents, this Court held that the Government had not proved its case.[52]

In upholding the price term in the Westinghouse manufacturing license, the Court reiterated the same point, noting that at common law:

> It is well settled, as already said, that, where a patentee makes the patented article and sells it, he can exercise no further control over what the purchaser may wish to do with the article after his purchase. It has passed beyond the scope of the patentee's rights.[53]

C. The Cartel Price-Fixing Cases

The critical distinction between the right to control the price charged (1) by one who has purchased a patented product for full consideration in an authorized and unconditional sale; and (2) by one who manufactures a patented product under license from the patentee was again reinforced in a series of cases decided between 1940 an 1964.[54] Although the Gov-

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[51] *Id.* at 485 (emphasis supplied).

[52] *See id.* at 488.

[53] *Id.* at 489 (citing *Adams v. Burke*, 84 U.S. (17 Wall.) 453 (1873); *E. Bement & Sons v. National Harrow Co.*, 186 U.S. 70 (1902) ("*National Harrow*").

[54] *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436 (1940); *United States v. Univis Lens Co.*, 316 U.S. 241 (1942); *United States v. Masonite Corp.*, 316 U.S. 265 (1942); *United States v. Line Material Co.*, 333 U.S. 287 (1948); *United States v. United*

ernment claims to find support for its position in five of these cases, their relevance for that purpose remains obscure, particularly in view of the fact that they all appear both (1) to confirm the continuing vitality of the scope of the patent threshold standard to which the FTC objects so strenuously; and (2) to indicate that the validity of the underlying patent must be assumed for purposes of the antitrust analysis.

D. The Federal Circuit's Approach To The Scope Of The Patent Rule

In the more than thirty years since the Court of Appeals for the Federal Circuit was established, it has applied the scope of the patent standard in two important areas other than Hatch-Waxman reverse payment settlements. First, it has used the standard to craft a rule for establishing the equitable defense of patent misuse in areas where this Court has not yet acted. The leading case is *Mallinckrodt*.[55] Second, it has employed the standard to justify refusals to license and deal in patented goods. That leading case is *Xerox/ISO*, *supra*.

In *Mallinckrodt*, *supra*, 976 F.2d at 708, Judge Newman conducted an exhaustive review of this Court's cases and harmonized the controlling principles as follows: "The appropriate criterion is whether

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States Gypsum Co., 333 U.S. 364 (1948); *United States v. New Wrinkle*, 342 U.S. 371 (1952); *United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963); *Simpson v. Union Oil Co.*, 377 U.S. at 24.

[55] *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (Fed. Cir. 1992) ("*Mallinckrodt*"); *see also Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995 (Fed. Cir. 1986) ("Windsurfing"); *U.S. Philips Co. v. Int'l Trade Comm'n*, 424 F.3d 1179 (Fed. Cir. 2005) ("*Philips I*"); *Princo v. ITC*, *supra*.

Mallinckrodt's restriction is **reasonably within the patent grant**, or whether the patentee has ventured beyond the patent grant and into behavior having an anticompetitive effect not justifiable under the rule of reason.[55]

Xerox/ISO, represents another important chapter in the Federal Circuit's development and application of the threshold scope of the patent standard to refusals to deal in patented goods. As developed further, *infra*, the decision also represents a significant breakthrough in terms of the expansion of the treatment of this Court's *PRE* holding from a relatively narrow immunity holding to an evidentiary ruling of general application to the entirety of the patent-antitrust interface.

E. The Scope Of The Patent Rule As Applied To Reverse Payments

As applied to reverse payments, the scope of the patent rule has three parts and can be summarized as follows:

> An agreement settling a Hatch-Waxman patent infringement litigation cannot be found to violate Section 1 of the Sherman Act, 15 U.S.C. § 1 on the ground that it contains a reverse payment claim unless:
>
> 1. The patent under which the suit was brought is shown to have been fraudulently obtained;
>
> 2. The suit for the patent's enforcement is shown to have been objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits; or

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[55] *Mallinckrodt*, 976 F.2d at 708 (emphasis supplied).

3. Competition beyond the claimed subject matter or temporal scope of the right to exclude has been unreasonably restrained.

The three branches of this rule all derive from authoritative precedents issued by this Court. Each of the reverse payment appellate decisions to reach this Court save *K-Dur*, can be explained by its terms.

II. REVERSE PAYMENTS HAVE NEVER BEEN SHOWN DIRECTLY AND OBJECTIVELY TO RESULT IN AN ANTICOMPETITIVE EFFECT IN ANY RELEVANT PRODUCT MARKET, AND THIS COURT SHOULD CONFIRM THAT APPLICATION OF A "QUICK LOOK" RULE OF PRESUMPTIVE ILLEGALITY TO SUCH PAYMENTS IS COMPLETELY UNJUSTIFIED

The public portion of the FTC's campaign against reverse payments is now approaching its fifteenth year. Nevertheless, no federal court of appeals has ever found, absent some violation of the threshold scope of the patent standard, that an anticompetitive effect of a Hatch-Waxman reverse payment could be proved in any properly defined relevant product market before a district court or agency. Under the authoritative precedents of this Court, that fact alone forecloses the quick look presumptive illegality approach which the Government has been pressing since 2009 and which the Third Circuit erroneously adopted in *K-Dur*. No court of appeals has ever applied such a rule in any patent-antitrust or misuse case, and in *Princo v. ITC* the Federal Circuit squarely rejected the efforts of the FTC to impose one in an en banc opinion in which eight of the ten sitting judges joined.

The FTC has failed to fashion any viable theory as to why reverse payment settlements that satisfy the threshold scope of the patent adjunct to the rule of reason standard are not exempt from application of the antitrust laws. Under that threshold rule, the subjective strength or weakness of any Orange Book patent is simply irrelevant under this Court's precedents.[57]

Moreover, if a reverse payment settlement passes muster under the scope of the patent test, the federal appellate courts have repeatedly confirmed that there can be no competent objective proof of what a court would have ruled on validity. The FTC's alternative argument on putative entry date likewise is not susceptible of objective proof and, what is more, totally ignores the significance of the "at risk" entry problem under the peculiar asymmetrical economics imposed under the Hatch-Waxman Act.[58]

On the other hand, a large part of the Hatch-Waxman Act's enormous success certainly can be attributed to the subjective and objective assessments of patent strength which invariably are made by the technically sophisticated and well advised litigants who conclude these settlements. The FTC is wrong to conclude that the parties are not better

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[57] Any doubt on that score—along with the FTC's argument that Section 282 of the Patent Act can be read merely as a burden-shifting tool—evaporated with this Court's decision in *Microsoft Corp. v. i4i Ltd. Partnership*, 131 S.Ct. 2238, 2242, 2245-47 (2011). *See also American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350 (Fed Cir. 1984) (Rich, J.); *Radio Corp. of America v. Radio Eng'g Labs., Inc.*, 293 U.S. 1 (1931).

[58] Private plaintiffs are even worse off than the FTC, since Section 4 of the Clayton Act imposes even greater burdens upon a private plaintiff.

equipped than any potential trier of fact to determine what reasonable agreed entry dates should result from Hatch-Waxman settlements.

Finally, there is no reason whatsoever to make any distinction between Hatch-Waxman reverse payment terms and the large credits for legal expenses and infringement damages forgiveness for pre-settlement periods which represent common terms in standard patent infringement settlements.

Before a *per se* rule of illegality or a "quick look" rule of presumptive illegality can be applied or even contemplated, both the threshold scope of the patent test and the full or truncated rule of reason inquiry must be satisfied. This conclusion was fully anticipated in 2004 by the SG's *Andrx v. Kroger* Brief.[59]

Princo v. ITC, the final chapter of an important Federal Circuit case addressing the scope of the equitable doctrine of misuse, significantly affects patent pooling and rights clearance agreements for research joint ventures (RJVs) and standard setting organizations (SSOs).[60] The case was filed before the International Trade Commission (ITC) under Section 337, 19 U.S.C. § 1337, and sought to bar former licensees under six patents owned by U.S. Philips

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[59] As the SG phrased it in his 2004 *Andrx v. Kroger* Brief, "*per se* treatment is reserved for conduct that has a predictable and pernicious anticompetitive effect." *Id.* at 7. The Federal Circuit's decision in *Cipro IV* illustrates how the appropriate truncated rule of reason analysis should be applied after the settlement terms have been found exempt from antitrust liability under the scope of the patent rule. The Federal Circuit's approach, moreover, is internally consistent with that of the analogous Second and Eleventh Circuit formulations.

[60] *See generally Gasoline Cracking.*

Corp. ("Philips") from importing foreign CD-R and CDR-W storage discs into the United States.

The administrative law judge ("ALJ") initially found the Philips patents valid and infringed but unenforceable for patent misuse. The Commission affirmed. A panel of the Federal Circuit reversed in *Philips I*,[61] a scholarly and well-reasoned opinion by Judge Bryson, ruling that the package-licensing allegations of defendants were neither sufficient to make out a case of per se misuse under this Court's precedents, nor supported by adequate proof of some anticompetitive effect in some properly defined relevant product market.

The FTC had filed an amicus brief after the period for briefing by the parties and amici curiae had closed,[62] arguing – just as it does here, and citing virtually the same authorities – that the Federal Circuit could reverse the injunction against importation without finding an anticompetitive effect in some properly determined relevant product market by employing the "quick look" analysis to determine that the challenged agreement was "inherently suspect."[63]

The Federal Circuit rejected the FTC's position in the pertinent portion of Judge Bryson's opinion (Part II.C) by an 8-2 vote, with only the reversed panel majority accepting the FTC's arguments. The rea-

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[61] *U.S. Philips Corp. v. Int'l Trade Comm'n*, 424 F.3d 1179 (Fed. Cir. 2005).

[62] "Brief Of Amicus Curiae Federal Trade Commission On Rehearing En Banc Supporting Neither Party in *Princo v. ITC*" ("FTC *Princo v. ITC Brief*"). *See also* NYIPLA's *Princo v. ITC* Brief.

[63] *Id.* at 19, 21.

soning of the majority speaks volumes and should be applied directly to this case:

> The dissenting opinion seems to sidestep the Commission's adverse factual findings by arguing that the burden of proof should have been placed on Philips, not *Princo* * * *. The dissent advocates a "quick look" rule of reason analysis on the ground that any agreement not to compete is inherently suspect and that competitive harm therefore should be presumed.

After reviewing *California Dental Ass'n v. F.T.C.*, 526 U.S. 756 (1999) ("*CDA*"), and *Texaco Inc. v. Dagher*, 547 U.S. 1 (2006) ("*Dagher*"), however, the majority went on to hold that:

> [T]he Supreme Court has cautioned that presumptions of anticompetitiveness should not be lightly invoked [citing BMI[84]]
>
> Rather the Court has stated:
>
> [B]efore a theoretical claim of anticompetitive effects can justify shifting to a defendant the burden to show empirical evidence of procompetitive effects, as quick look analysis in effect requires, there must be some indication that the court making the decision has properly identified the theoretical basis for the anticompetitive effects and considered whether the effects are actually anticompetitive. Where, as here, the circumstances of the restriction are somewhat complex, assumption alone will not do.[85]

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[84] *Broad. Music, Inc. v. Columbia Broadcast Sys.*, 441 U.S. 1, 8-9 (1979) ("*BMI*").

[85] *Princo v. ITC*, 616 F.3d at 1339 (citing *CDA*, 526 U.S. at 776, n.12).

III. APPLICATION OF A RULE OF PRESUMPTIVE ILLEGALITY TO REVERSE PAYMENTS ALSO IS PRECLUDED BY THE LETTER AND SPIRIT OF *PROFESSIONAL REAL ESTATE*

It is completely permissible under the antitrust laws for the branded manufacturers to litigate fiercely and attempt to "try their losers" to final judgment so long as the applicable standard of *PRE* is not violated. The Government makes no attempt to distinguish *PRE*, or to suggest that *Xerox/ISO* and *Asahi Glass* were wrong, respectively, to extend *PRE* as an evidentiary rule of general application to refusals to deal in patented goods in 2000 and to Hatch-Waxman reverse payment settlements in 2003. Indeed, the FTC and the ATD have tried to ignore *PRE* ever since *Xerox/ISO* was first cited to this Court by the SG in 2004.

This Court should announce that the rule of *PRE* both (1) fixes the level and nature of the proof required to satisfy the "sham" exception to the *Noerr-Pennington* immunity doctrine, and (2) applies the same standard to the Government's burden of proving an anticompetitive effect in some properly defined relevant product market in any full or truncated rule of reason trial that may be required (a) not only to assess Hatch-Waxman reverse payment settlements, (b) but also to adjudicate other alleged patent-antitrust matters to which the threshold scope of the patent standard must be applied, such as the refusals to deal in patented goods addressed in *Xerox/ISO*.

There, after finding that the threshold scope of the patent standard had been met the court ruled that

> our inquiry is at an end. Xerox was under no obligation to sell or license its patented parts and did not violate the antitrust laws by refusing to do so.[86]

In reaching this result, the court relied heavily upon *PRE* to reject the approach applied by the Ninth Circuit in *Kodak/ITS*,[87] under which the jury had been permitted to assess whether the patentee's conduct had been "pretextual." Taking note of the statement in *PRE* that "if a suit is not objectively baseless, an antitrust defendant's subjective motivation is immaterial," the Federal Circuit refused to follow *Kodak/ITS*, reasoning that:

> [w]e see no more reason to inquire into the subjective motivation of Xerox in refusing to sell or license its patented works than we found in evaluating the subjective motivation of a patentee in bringing suit to enforce that same right.[88]

After the petition for certiorari had been filed in *CSU v. Xerox*, the SG filed an amicus brief pursuant to another SVSG order addressing both of the arguments which the Federal Circuit had accepted in *Xerox/ISO*.[89] The SG took no position, however, on the Federal Circuit's rejection of *Kodak/ITS* based

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[86] *Xerox/ISO, supra*, 203 F.3d at 1328.

[87] *Image Tech. Servs., Inc. v. Eastman Kodak Co.*, 125 F.3d 1195 (9th Cir. 1997) ("*Kodak/ITS*").

[88] *Xerox/ISO*, 203 F.3d at 1327. *See also* NYIPLA's *Xerox/ISO* Brief.

[89] SG's *CSU v. Xerox Brief*.

upon PRE, instead recommending that the issue be left to "percolate further."[70]

When the FTC filed a certiorari petition seeking to reverse its court of appeals loss in *Schering-Plough*, the SG again filed an *amicus* brief in response to an SVSG order. The SG criticized certain aspects of "the FTC's approach," which was perceived "to place undue weight on the parties' subjective views,"[71] and recommended that certiorari be denied.

Given the very real prospect of treble damages and even the potential for criminal liability, bright line antitrust standards must be clear, objective and fair. Extended application of the rule of *PRE* at the patent-antitrust interface will provide just such a standard.

IV. APPLICATION OF A RULE OF PRESUMPTIVE ILLEGALITY TO REVERSE PAYMENTS WOULD THREATEN THE ENORMOUS SUCCESS OF THE HATCH-WAXMAN ACT AND COULD UNDERMINE THE RATIONALE FOR ITS ENACTMENT BY CONGRESS

One principal objective of Congress in enacting the Hatch-Waxman Act was to maximize challenges to Orange Book patents well before their expiration and thereby increase the availability of generic substitutes for branded innovator drugs at earlier dates. We already have seen that, judged by any applicable standard, that aspect of the legislation has been enormously successful.

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[70] *Id.* at 16.

[71] *Id.* at 12.

Another involves the safe harbor provisions of Section 271(e) of the Patent Act, 35 U.S.C. § 271(e)(1), as discussed by this Court in *Merck v. Integra*.[73] By overruling the Federal Circuit's *Roche v. Bolar* decision in the 1984 legislation,[73] Congress eliminated the *de facto* temporal extension of the monopoly which invariably delayed generic entry due to the regulatory requirements of the FDA.[74]

While profits of branded innovators were pinched by both aspects of the new legislation, Congress realized that the R&D burden for financing new drug research and development would remain on the branded innovators.

A. The FTC Has Conceded That Imposition Of A Quick Look Rule Of Presumptive Illegality Would Reduce Net Generic Challenges

An alleged savings target of $3.5 billion a year may translate to good public relations for an agency with a $300 million budget,[75] but that figure becomes

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[73] *Merck KGaA v. Integra Lifesciences, Ltd.*, 545 U.S. 193 (2005) ("*Merck v. Integra*").

[73] *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984) ("*Roche v. Bolar*").

[74] *See* "Brief Of New York Intellectual Property Law Association As *Amicus Curiae* In Support Of Petitioner in *Merck v. Integra*" ("NYIPLA *Merck v. Integra* Brief").

[75] When FTC Chairman Jon Leibowitz spoke last September at Fordham University, he cited the staff estimates from the 2010 Pay-For-Delay Study as grounds for self-congratulation on the agency's role in achieving the *K-Dur* decision: "We're a tiny agency by Washington standards ... and if an agency of $300 million a year can save $3.5 billion a year for American consumers, I think that's a terrific accomplishment." FTC

considerably less attractive when compared to a total annual market of almost $200 billion which may well be threatened by the FTC's crusade.

Irrespective of who will eventually win the battle of economic experts, the FTC already has conceded that the rule it asks this Court to impose would have the effect of reducing net challenges to Orange Book patents.

Indeed, both the FTC and the Third Circuit panel in *K-Dur* have recognized that any statute or judicial rule making reverse payments unlawful under the antitrust laws inevitably would reduce the net number of validity challenges under the Hatch-Waxman Act. The FTC's concession is set forth in footnote 24 of the 2010 Pay-For-Delay Study, which goes on to suggest that the effect of this reduction "would likely be very low" predicated solely upon the FTC's assertion that "only 24% of all cases settled" under the Hatch-Waxman Act contain reverse payment terms.

NYIPLA respectfully suggests that changes which threaten to reverse the gains in early generic entry heretofore achieved simply cannot be risked upon such tenuous evidence.

B. Limiting Generic Flexibility Likewise Would Reduce Net Challenges

The FTC today also seems oblivious to the fact that freedom to conclude reverse payment settlements is important to the vigorous competition within the generic sector which must be preserved to ensure the continuing success of Hatch-Waxman. In 2004,

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Sets Sights on High Court Pay-For-Delay-Fight, *available at* http://law.fordham.edu/newsroom/ 27940.htm.

however, the catalogue of concessions made in the Commission's *Schering-Plough* decision, as set forth in the SG's *Andrx v. Kroger* Brief and identified as "legitimate justifications" for reverse payment settlements, included both (1) that a "cash starved" generic drug firm might well benefit from the availability of "some up-front support from the pioneer manufacturer," and (2) that a "judgment-proof generic manufacturer whose downside risks of damage exposure are small."

We have also seen from the discussion, *supra*, of the GPhA *Tamoxifen* Brief, that freedom to settle and litigation flexibility based upon adequate cash reserves represent important factors for potential generic manufacturers in achieving the goals of the Hatch-Waxman Act.

The generic manufacturer has no fiduciary relationship to the public, and answers only to its shareholders. It has no obligation to take any case to final judgment and its interest is to negotiate whatever mix of early entry and reverse payment which best suits its optimum cash position.

Within that framework, the generic segment of the industry was disappointed to learn of the recent comments of Marcus Meier, the FTC's assistant director for health care in the Bureau of Competition, at the annual meeting of the New York State Bar Association. Meier simply dismissed the notion previously accepted by the full Commission and the SG that reverse payment settlements should be deemed pro-competitive when they are employed to restore the litigation war chests of cash poor generics: "Sometimes businesses succeed and sometime businesses

fail, and that's just too bad. That doesn't justify an anti-competitive settlement."[76]

CONCLUSION

For the foregoing reasons, the judgment of the court of appeals should be affirmed.

Respectfully submitted,

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[76] *See* Pay-For-Delay Antitrust Test Sets Bar Too High: FTC Official (Jan. 24, 2013), available at http://www.law360.com/articles/409984/pay-for-delay-antitrust-test-sets-bar-too-high-ftc-official.

AMICUS CURIAE BRIEF

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Petitioner,

v.

WATSON PHARMACEUTICALS, INC., *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

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STATEMENT OF INTEREST OF *AMICI CURIAE*

The Academic *Amici* are professors of economics, business, innovation, antitrust law, and intellectual property (IP) law. (A list of signatories is attached as Appendix A.) Their sole interest in this case is to ensure that patent and antitrust law develop in a way that serves the public interest and public health by promoting both innovation and competition.

The American Antitrust Institute ("AAI") is an independent and non-profit education, research, and advocacy organization devoted to advancing the role of competition in the economy, protecting consumers, and sustaining the vitality of the antitrust laws. AAI is managed by its Board of Directors, with the guidance of an Advisory Board that consists of more than 130 prominent antitrust lawyers, law professors, economists, and business leaders.[1]

Amici have filed this brief because they believe that the ruling of the court below is flawed and seriously threatens to undermine competition in the pharmaceutical industry. If affirmed, the opinion would result in severe anticompetitive harm and would upset a carefully crafted statutory scheme designed to prevent weak or narrow patents from blocking the entry of affordable generic drugs.

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1. No person other than *amici curiae* or their counsel authored this brief in whole or in part or made a monetary contribution intended to fund its preparation or submission. The parties have consented to the filing of this brief and such consents are being lodged herewith. AAI's Board of Directors has approved this filing for AAI. The individual views of Advisory Board members may differ from AAI's positions.

INTRODUCTION AND SUMMARY OF ARGUMENT

Antitrust law protects markets by preventing actual and potential competitors from colluding to harm consumers or exclude rivals. Patent law is designed to encourage innovation by giving inventors a right to exclude others from the patented product. For more than a century, courts have struggled to balance these two interests in the service of a dynamic, competitive economy.

These concerns were at the core of the Hatch-Waxman Act, Congress's framework for balancing patent and antitrust law in the pharmaceutical industry. A central tool in that balance was the encouragement of generic competition by offering a period of exclusivity to the first generic to challenge a brand firm's patent, claiming invalidity or non-infringement. The goal of exclusivity was to encourage generic manufacturers to challenge weak patents and enter the market earlier with cheaper drugs. But this carefully crafted scheme has been upended by brands' payments of millions of dollars to generics to abandon their patent challenges and delay entering the market. These "exclusion payments" or "reverse payments" violate basic antitrust principles, and deprive consumers of low-cost generics, costing billions of dollars a year and ensuring that many Americans are not able to afford necessary medicines.

Exclusion-payment settlements fly in the face of not only antitrust law and the regulatory regime but also patent law. This Court has recognized the important public policy interest served by challenging weak patents. Given the burdens confronting the U.S. Patent and Trademark

Office (PTO) and growing concerns over patent quality, this policy is as critical now as it ever was.

The court of appeals upheld the exclusion-payment settlement in this case by relying on a test based on the "scope of the patent," concluding that any settlement that was within the potential scope of the patent was entirely insulated from antitrust scrutiny. *F.T.C. v. Watson Pharmaceuticals, Inc.*, 677 F.3d 1298, 1306 (11th Cir. 2012). This analysis was not appropriate as a matter of either antitrust or patent law. Antitrust law has long forbidden agreements among horizontal competitors to allocate markets, which is the practical result when brands pay generics to drop challenges to weak patents and delay entering the market instead.

And while patent law properly limits competition in some respects, it does so only subject to the limits set forth in the Patent Act. In particular, patent policy not only permits legal challenges to weak patents; it affirmatively encourages those challenges. The court of appeals turned that policy on its head, permitting a patent owner to pay a competitor to avoid the very challenge the law encourages. The scope-of-the-patent test adopted by the court below allows a patentee to convert an initial determination by the PTO to grant a patent into a final, unreviewable conclusion that the patent is necessarily valid, and to do so with no judicial scrutiny whatsoever.

The patent grant itself provides only a presumption of validity. The Eleventh Circuit rule effectively converted that rebuttable (and oft-rebutted) presumption into an irrebuttable one. And it did so in this case in the face of evidence—a large monetary payment by the patentee to

the defendant to drop its validity challenge—that suggests there was good reason for the parties to think at the time they settled the case that this particular patent was invalid or not infringed. Such a rule is inappropriate, as the facts of this case make clear.

In fiscal year 2012, the FTC reported a record forty settlements in which brands paid generics to delay entering the market. Bureau of Competition, FTC, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2012*, http://www.ftc.gov/os/2013/01/130117mmareport.pdf. If this Court affirms the decision below, this trend would only accelerate. For all antitrust speed bumps to anticompetitive settlements would be removed, allowing brands to pay generics any amount of money they wish to block generic entry for the entire patent term.

The patents at the heart of exclusion-payment agreements often cause concern. They frequently cover not the drug's active ingredient but narrower aspects like the formulation or method of use that are less innovative and bear more potential for anticompetitive mischief. They are often added late in the game, after the patent on the active ingredient has expired. Indeed, in this case, the patent covered the use of a particular testosterone gel formulation even though pharmaceutical gel products have been available for decades and synthetic testosterone was artificially synthesized as early as 1935.

Commentators have proposed a variety of more suitable approaches to exclusion-payment settlements,

including presumptive illegality. These tests recognize the potentially severe anticompetitive effects of exclusion payments while also allowing the settling parties to offer justifications for their facially anticompetitive agreement.

Amici support reversal of the decision below, which short-circuited analysis of conduct that could be blatantly anticompetitive and that upends important policies at the core of the Hatch-Waxman Act and patent law. *Amici* support a more traditional antitrust framework based on a quick-look analysis that treats exclusion payments as presumptively unlawful.

ARGUMENT

I. THE HATCH-WAXMAN ACT DOES NOT SUPPORT EXCLUSION PAYMENTS

As this Court has made clear, it is appropriate for antitrust courts to "be attuned to the particular structure and circumstances of the industry at issue." *Verizon Commc'ns v. Law Offices of Curtis V. Trinko*, 540 U.S. 398, 411 (2004). Determining the appropriate antitrust rule in a regulated industry requires that the analysis "recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies." *Ibid.* Congress resolved the tension between the patent and antitrust laws in this context by enacting the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly known as the Hatch-Waxman Act. The legislation emphasized the crucial role of generics in challenging invalid and non-infringed patents.

A. The Hatch-Waxman Act Sought To Promote Generic Competition and Encourage Brand Innovation

In the Hatch-Waxman Act, Congress enacted a complex regulatory regime to foster drug innovation and competition. The pharmaceutical marketplace in the early 1980s suffered from sparse generic entry and stifled brand-drug firm innovation.

Generic drugs have the same active ingredients as brand drugs. At the time of the Hatch-Waxman Act, however, generic firms needed to undertake lengthy, expensive trials to demonstrate safety and effectiveness. Approval by the U.S. Food and Drug Administration (FDA) took years, and because the required tests constituted infringement, generics could not even begin the process during the patent term. At the time Congress enacted Hatch-Waxman, there was no generic on the market for 150 brand-name drugs whose patents had already expired. H.R. REP. No. 98-857, pt. 1, at 17 (1984).

The Act's drafters lamented the "practical extension" of the patentee's "monopoly position" beyond expiration of the patent. H.R. REP. No. 98-857, pt. 2, at 4. They thus sought to "make available more low cost generic drugs." H.R. REP. No. 98-857, pt. 1, at 14. Generic competition would save the federal and state governments millions of dollars each year. And given that older Americans used nearly 25 percent of prescription drugs, *id.* at 17, competition would "do more to contain the cost of elderly care than perhaps anything else this Congress has passed." 130 CONG. REC. 24427 (Sept. 6, 1984) (statement of Rep. Waxman).

The first tool the legislature created to accelerate generic entry was the Abbreviated New Drug Application ("ANDA") process that allowed generic firms to rely on the brand drug's safety and effectiveness studies and avoid the expensive and lengthy new-drug-application process. 21 U.S.C. §§ 355(j)(2)(A), 355(j)(8)(B). Second, Congress resuscitated the experimental use defense, exempting from infringement the manufacture, use, or sale of a patented invention for uses "reasonably related to the development and submission of information" under a federal law regulating the manufacture, use, or sale of drugs. 35 U.S.C. § 271(e)(1). Third, Congress increased competition by creating a 180-day period of generic marketing exclusivity, reserved for the first generic to certify that the brand firm's patent was invalid or not infringed and enter the market before the patent expired.

In addition to promoting generic competition, the Act included several mechanisms to bolster incentives for brand-firm innovation. First, Congress increased the effective patent life by extending the patent term, with the extension currently amounting to half the time the drug is in clinical trials plus the period spent awaiting FDA approval after trials. 35 U.S.C. § 156(c). Second, Congress granted an automatic 30-month stay of FDA approval to patent holders who sue generic filers within 45 days. This period provides an additional exclusionary right benefiting brand firms that—even without obtaining a preliminary injunction or demonstrating entitlement to one—will not face generic competition for a substantial period of time. 21 U.S.C. § 355(j)(5)(B)(iii). Finally, Congress provided for periods of market exclusivity not based on patents, such as the four-year exclusivity period for a drug with a new active ingredient. 21 U.S.C. § 355(j)(5)(F)(ii).

The Act's drafters emphasized the equilibrium between competition and innovation. Representative Henry Waxman underscored the "fundamental balance of the bill." 130 CONG. REC. 24425 (Sept. 6, 1984). The Energy and Commerce Committee Report explained that allowing early generic challenges "fairly balances" the exclusionary rights of patent owners with the "rights of third parties" to contest validity and market products not covered by the patent. H.R. REP. No. 98-857, pt. 1, at 28. And the House Judiciary Committee noted that it "has merely done what the Congress has traditionally done in the area of intellectual property law[:] balance the need to stimulate innovation against the goal of furthering the public interest." H.R. REP. No. 98-857, pt. 2, at 30. Indeed, just last term this Court discerned in the Hatch-Waxman Act a purpose "[t]o facilitate the approval of generic drugs as soon as patents allow." *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012).

A central element of this equilibrium was the 180-day period of marketing exclusivity. This period was reserved for the first generic firm to successfully challenge a patent and introduce competition before the end of the patent term. When the FDA approves a new drug application ("NDA"), it lists the drug and any relevant patents in a publication known as the Orange Book. Before entering the market, a generic applicant must provide one of four certifications for each patent listed in the Orange Book relating to the relevant NDA. The first three certifications—no patent on the drug, an expired patent, and a promise to wait until the patent expires—do not result in periods of exclusivity. Only the "Paragraph IV" certification, by which the generic claims that the patent

is invalid or not infringed, leads to exclusivity. 21 U.S.C. § 355(j)(2)(A)(vii). The purpose of this exclusivity was to encourage challenges to invalid or improperly asserted patents.

B. Exclusion Payments Undermine the Hatch-Waxman Act

In the years since the passage of the Hatch-Waxman Act, the primary drafters of the legislation have expressed their disapproval of exclusion-payment settlements. Representative Waxman explained that such agreements "turn[] the . . . legislation on [its] head." Motion & Brief of Representative Henry A. Waxman as *Amicus Curiae* in Support of Petitioner at *1, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273), 2005 WL 2462026. Waxman emphasized that the purpose of the legislation was to promote generic competition, not to allow generics "to exact a portion of a brand-name manufacturer's monopoly profits in return for withholding entry into the market." *Ibid.* Senator Hatch similarly found such agreements "appalling." And his assessment mirrored that of Waxman in making clear that "[w]e did not wish to encourage situations where payments were made to generic firms not to sell generic drugs and not to allow multi-source generic competition." 148 CONG. REC. S7566 (daily ed. July 30, 2002).

As its drafters have recognized, the effectiveness of the Hatch-Waxman Act has been severely compromised by settlements like the one in this case. Although generic entry has burgeoned in the three decades since Congress enacted the law, generics are increasingly not serving their designated function. *See* Michael

A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 Mich. L. Rev. 37, 71 (2009) [Carrier, *Unsettling Settlements*]; C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1616 (2006) [Hemphill, *Paying for Delay*]; Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. Rev. 11, 25-26 (2004).

The 180-day bounty, in particular, has been twisted from an incentive for generics to challenge patents to a barrier to entry preventing challenge. By settling with the first challenger, the brand firm can significantly delay other generics' entrance into the market. *See* 1 Herbert Hovenkamp et al., *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* § 15.3, at 15-45 (2d ed. Supp. 2010); C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 Antitrust L.J. 947 (2011). Later generics would be less motivated to pursue a challenge since they would be further behind in the approval process, would not be entitled to the market exclusivity period, and would receive a return dependent on the outcome of the first filer's suit. Hemphill, *Paying for Delay*, at 1586. Such hurdles loom large given the costs of developing generic drugs, receiving FDA approval, and pursuing patent litigation.

The Hatch-Waxman Act encouraged challenges to invalid patents in order to promote earlier generic market entry and lower prices for consumers. But the carefully balanced regulatory regime is not working as intended to promote competition. And exclusion-payment settlements are the reason.

II. EXCLUSION PAYMENTS ARE FACIALLY ANTICOMPETITIVE

Of all the types of business activity subject to the Sherman Act, agreements by which competitors divide markets are the most dangerous. Market division restricts *all* competition between the parties on *all* grounds. Even price fixing (unlawful as it is) allows the parties to compete on factors other than price.

This Court has held that the Sherman Act prohibits not only agreements that reduce competition among existing competitors, but also those that restrain potential market entry. In *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49-50 (1990) (per curiam), the Court found that an agreement by which rivals "agreed not to compete in the other's territories" was anticompetitive. *See also* Robert H. Bork, *The Antitrust Paradox: A Policy at War with Itself* 269 (1993 ed.). And the leading antitrust treatise makes clear that "the law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition." 12 Herbert Hovenkamp, *Antitrust Law* ¶ 2030b, at 220 (3d ed. 2012).

Brand firms such as Solvay have entered into exclusion-payment settlements with generics. Pursuant to these agreements, the generic firm (1) drops its patent challenge and (2) agrees to delay entering the market. In return, the brand pays the generic millions—sometimes hundreds of millions—of dollars.

These payments are profitable to the settling parties precisely because they eliminate actual or potential competition. Because the brand firm makes more by

keeping the generic out of the market than the two parties would receive by competing in the market, the parties have an incentive to cede the market to the brand firm and split the monopoly profits. Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 Rand J. Econ. 391, 408 (2003) [Shapiro, *Antitrust Limits*]. The brand then can use a portion of this additional profit from delayed competition to pay the generic. In fact, the brand could even pay more than the generic would have received from *winning* its patent challenge and *entering* the market. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) (approving exclusion payment of $398 million, more than the generic would have made even if it had won the case and entered).

Exclusion payments are fairly characterized as the brand's purchase of the generic's agreement to cease or delay its efforts to enter the market and compete against the patented drug. An agreement concerning the generic entry date, without any cash payment, will normally reflect the odds of the parties' success in patent litigation: the more likely the patentee is to win the case, the more it can rely on the patent itself to exclude competition. 1 Herbert Hovenkamp et al., *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* § 15.3, at 15-45 (2d ed. Supp. 2010). But paying generics to stay out of the market changes that calculus. A brand is likely to gain additional exclusivity by supplementing this entry-date agreement with a payment to the generic. The quid pro quo for the payment would appear to be the generic's agreement to stay out of the market beyond the expected entry date resulting from litigation.

Settlements by which brands pay generics not to enter the market pose dangers analogous to territorial market allocation. Instead of allocating geographic space, they allocate time, with the brand blocking *all* competition for a period of time. It is plain that a naked agreement by a patent holder to pay a competitor or potential competitor not to challenge its patent would be per se illegal under *Palmer*. The fact that such an agreement is contained in a settlement of patent litigation may suggest that procompetitive justifications could be entertained, but is hardly a defense in and of itself. On the contrary, if the terms of a patent settlement unreasonably restrain competition, they violate the Sherman Act. *United States v. Singer Mfg. Co.*, 374 U.S. 174, 194-95 (1963) (striking down a patent settlement excluding foreign competitors from the U.S. market).

With an exclusion payment, the brand firm buys assurance that its patent will not be invalidated—something that patent law alone does not give and the Hatch-Waxman Act did not contemplate.

III. THE MERE FACT OF A PATENT CANNOT JUSTIFY ANTICOMPETITIVE EXCLUSION PAYMENTS

The court of appeals concluded that "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." 677 F.2d at 1322.[2] The fact that one of the antitrust defendants had a

2. The two prongs of liability not relying on scope are more ephemeral than real, making the Eleventh Circuit's test effectively one of per se *legality*. The test for sham litigation requires an

patent that the law presumed valid, it concluded, meant that any anticompetitive harm must flow from the patent and not from the exclusion-payment settlement. In so concluding, the court below committed a logical fallacy. The fact that a settlement reaching a product *outside* the scope of the patent is per se illegal does not mean that one falling *within* the potential, facial scope of the patent is automatically valid. Michael A. Carrier, *Why the "Scope of the Patent" Test Cannot Solve the Drug Patent Settlement Problem*, 16 Stan. Tech. L. Rev. 1, 5 (2012) [Carrier, *Scope Test*]. In any event, the Eleventh Circuit's scope-of-the-patent test also misunderstands actual patent practice, patent policy, and patent law.

"objective baselessness," *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61 (1993), that is extremely difficult to satisfy given the standard's lack of teeth, the complexities of patent litigation, and the fact that a generic that initially alleges patent invalidity and non-infringement later (after receiving millions of dollars) changes its tune. 1 Herbert Hovenkamp et al., *IP and Antitrust* §11.2d (2d ed. 2010). Additionally, the test is grounded in First Amendment protections not relevant when the parties have withdrawn any petition in favor of a private agreement.

The other prong, fraud on the patent office, also sets a high bar not likely to be shown in these cases. *Walker Process Equip. Corp. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965); 1 Herbert Hovenkamp et al., *IP and Antitrust* §11.2f (2d ed. 2010) ("A *Walker Process* claim requires a high burden of proof .... Only a few appellate decisions have affirmed a finding of *Walker Process* fraud applying the Federal Circuit's current strict standards.").

A. The Patent Office Frequently Issues Invalid Patents

The grant of a patent reflects an initial judgment by the PTO that an invention is patentable. Such a judgment comes after limited scrutiny with examiners having, on average, less than 20 hours to read an application, search for prior art, evaluate patentability, and reach and write up conclusions. Fed. Trade Comm'n, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, Exec. Summary, at 9-10 (2003).

Because of this limited examination, litigation plays a crucial role in ferreting out invalid patents. It would take "an enormous investment of time and resources" for the PTO to gather the information needed to make appropriate validity decisions. Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 Nw. U. L. Rev. 1495, 1531 (2001). These decisions "can be made much more efficiently in litigation" since "only a tiny percentage of patents are ever litigated or even licensed to others." *Ibid.* When a patent is asserted in litigation, accused infringers are entitled to demonstrate that the patent should not have issued.

The role of litigation in uncovering invalid patents is essential given how many patents issued by the Patent Office are later found to be invalid. Empirical studies have consistently shown that at least 40% of granted patents that are litigated to decision are invalid.[3] These

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3. *See* John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA L.Q. 185, 205 (1998) (courts invalidated 46% of patents between 1989

figures are even higher in the pharmaceutical industry, with a study by the FTC finding that generics prevailed in 73% of paragraph IV challenges between 1992 and 2000. FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* 16 (2002), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

B. This Court Has Recognized the Importance of Challenging Invalid Patents

This Court explained in *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969), that a patent "simply represents a legal conclusion reached by the Patent Office" that is "predicated on factors as to which reasonable men can differ widely." The Patent Office "is often obliged to reach its decision in an ex parte proceeding, without the aid of the arguments which could be advanced by parties interested in proving patent invalidity." *Ibid.* As a result, "it does not seem to us to be unfair to require a patentee to defend the Patent Office's judgment when his licensee places the question in issue." *Ibid.*

Lear's conclusion did not simply rest on the realities of an imperfect PTO. Rather, it reflected an affirmative policy judgment that invalidating weak patents served the public good. The Court emphasized "the important public interest in permitting full and free competition in the use

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and 1996); Kimberly A. Moore, *Judges, Juries, and Patent Cases – An Empirical Peek Inside the Black Box*, 99 Mich. L. Rev. 365, 385 (2000) (alleged infringer prevailed in 42% of patent cases that reached trial between 1983 and 1999); University of Houston Law Center, Decisions for 2000-2004, Issue Codes 01-16, 23, 24, *available at* http://www.patstats.org/2000-04.htm (in patent cases between 2000 and 2004, courts found 43% of patents invalid and 75% not infringed).

of ideas which are in reality a part of the public domain." *Ibid.* Nor was *Lear* alone. This Court has repeatedly emphasized the importance of testing weak patents and protecting the public from monopolies based on invalid patents. *See, e.g., MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 137 (2007) (licensees have standing to challenge patent validity or infringement without repudiating their licenses); *United States v. Glaxo Group, Ltd.*, 410 U.S. 52, 57 (1973) (emphasizing "public interest in free competition" in concluding that licensee in antitrust suit "may attack the validity of the patent under which he is licensed even though he has agreed not to do so in his license"); *Blonder-Tongue Labs. v. Univ. of Illinois Found.*, 402 U.S. 313, 349-50 (1971) (allowing alleged infringer to claim estoppel where patent previously declared invalid); *Microsoft Corp. v. i4i LLP*, 131 S. Ct. 2238, 2253 (2011) (Breyer, J., concurring) (offering measures designed to "increase the likelihood that discoveries or inventions will not receive legal protection where none is due").

Challenging invalid patents is even more important today than it was at the time this Court decided *Lear*. The burdens on the Patent Office have only increased in the past four decades as the number of patent applications filed has skyrocketed to over 500,000 per year, more than five times the number filed when *Lear* was decided. U.S. PTO, *U.S. Patent Statistics Chart*, http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm.

C. The Patents at the Heart of Exclusion-Payment Settlements Present Concern

While many of the concerns expressed about the validity of patents issued by the PTO have arisen in the context of software and business methods, the problem

of invalid patents is by no means limited to those industries. In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 1294 (2012), this Court concluded that medical tests that relied on correlations between treatment and drug dosages were not patentable, explaining that the process involved "well-understood, routine, conventional activity" that had been "previously engaged in by researchers in the field." Nor is overbroad patent protection costless. As the Court recognized in *Prometheus*, patent exclusivity "can impede the flow of information that might permit, indeed spur, invention" by "raising the price of using the patented ideas once created, requiring potential users to conduct costly and time-consuming searches of existing patents and pending patent applications, and requiring the negotiation of complex licensing arrangements." *Id. at* 1305.

The risk is particularly great in the pharmaceutical industry because the regulatory scheme governing that industry, the Hatch-Waxman Act, gives patentees substantial benefits merely for filing a patent suit, including an automatic 30-month stay of generic entry. 21 U.S.C. § 355(j)(5)(B)(iii). This has led many pharmaceutical companies to file suit on weak patents in order to delay competition and to engage in other forms of regulatory subterfuge. In *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670 (2012), this Court allowed generics to challenge brand firms' overly broad "use codes," which describe patents, are not reviewed by the FDA, and block generic competition. This Court found that, in enacting the statute, Congress "sees, raises, and bests" the arguments of brand companies based on "gamesmanship." *Id. at* 1682. And it emphasized the purpose of the Hatch-Waxman Act to encourage generic

entry as soon as possible when a patent was invalid or not infringed. *Id. at* 1688.

Generic challenges to drugs are disproportionately brought against weak patents, not strong ones. New drug compounds provide most of the social value of pharmaceutical inventions. And in fact, patents covering a new active ingredient—the compound itself—tend to be strong and (in satisfying the requirement of bioequivalence) more likely to be infringed by the production of the generic drug. C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. Empirical Legal Stud. 613, 621 (2011) [Hemphill & Sampat, *Generic Challenges*].

Drug companies, however, are increasingly patenting and asserting ancillary, non-active ingredients, like a formulation, dissolution profile, or method of use. *Id.* at 615. Those patents are less innovative (and so less likely to be valid) and easier to avoid. Asserting them accordingly bears more potential for anticompetitive mischief. For under the regulatory regime, even a weak patent or one on a minor advance like a method of delivery can prevent market entry by the generic.

Empirical research has shown that generics disproportionately challenge these weaker "follow-on" patents, not those covering the active ingredient. Hemphill & Sampat, *Generic Challenges*, at 643. In particular, non-active-ingredient patents and drugs with "more questionable" patents and "greater patent life generated by late patents" are "much more likely to draw challenges." *Ibid.* While generics challenge 75% of non-active-ingredient patents, they challenge only 29% of

active-ingredient patents. C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 Journal of Health Economics 327, 334 (2012). In short, "generic drug makers use challenges as a route to entry" when brand drugs have "patents of questionable validity or scope" that "would, in the absence of challenges, block competition." Hemphill & Sampat, *Generic Challenges*, at 615.

This case involves just such a narrow, potentially questionable patent. The active ingredient, synthetic testosterone, was artificially synthesized in 1935 and has been available in drug products since the 1950s. Second Amended Complaint for Injunctive and Other Equitable Relief, *FTC v. Watson*, No. 1:09-CV-00955-TWT ¶ 31 (N.D. Ga. May 28, 2009) [Complaint]. Even pharmaceutical gel products have been available for decades. *Ibid.* The patent on AndroGel® at issue in this case, however, only covers the use of a particular gel formulation containing ingredients in certain amounts. *Id.* ¶ 39.

The law need not permit anticompetitive settlements in an effort to protect strong patents. Generics overwhelmingly challenge weak patents used to block competition. When those challenges are allowed to proceed, the generic prevails nearly three times in four. FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* 16 (2002), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf. And generics would be even more likely to focus their attention on weak patents if exclusion-payment settlements were deemed presumptively illegal. Some generics today may challenge strong patents in the hopes of being paid to drop the challenge. But if that payment is illegal, generics would focus their attention

precisely where public policy wants them to: on patents they think they can defeat in court.

D. The Presumption of Patent Validity Does Not Justify Exclusion-Payment Settlements

The presumption of validity is an evidentiary device designed to establish the standard of proof; it is not a substantive judgment that the PTO's decision was correct. *See Microsoft Corp.*, 131 S. Ct. at 2245; *id. at* 2253 (Breyer, J., concurring) ("[I]n this area of law as in others the evidentiary standard of proof applies to questions of fact and not to questions of law . . . Where the ultimate question of patent validity turns on the correct answer to legal questions—what these subsidiary legal standards mean or how they apply to the facts as given—today's strict standard of proof has no application."); *Reckendorfer v. Faber*, 92 U.S. 347, 355 (1875) (patent is "a prima facie right only . . . subject to an examination by the courts"). Indeed, the Federal Circuit, the court of appeals with jurisdiction over patent cases, has recognized that the presumption of validity is merely a procedural device with no substantive impact. *In re Etter*, 756 F.2d 852, 856 (Fed. Cir. 1985); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983).

As the evidence discussed above indicates, while issued patents are presumed valid, 35 U.S.C. § 282, that presumption is far from an irrebuttable one. Indeed, it is quite often rebutted in practice. One flaw in the court of appeals' scope-of-the-patent test is that it unwittingly transformed a procedural device for allocating the burden of proof into an irrebuttable presumption, a position this Court has repudiated. *Reckendorfer*, 92 U.S. at 355. By

presuming that Solvay's payment was within the scope of the patent, the court irrebuttably assumed that the patent was valid and infringed. *See In re K-Dur Antitrust Litigation*, 686 F.3d 197, 214 (3d Cir. 2012) (noting that the "scope of the patent" test "assumes away the question being litigated in the underlying patent suit, enforcing a presumption that the patent holder would have prevailed"); Carrier, *Scope Test*, at 5-6.[4] A presumption of validity does not entitle a patentee to evade the test of patent litigation any more than a criminal defendant's presumption of innocence entitles him to avoid trial.

The illogic of treating a burden of proof as having conclusive substantive effect, as the court below did here, can readily be illustrated. While an accused infringer must demonstrate the invalidity of a patent by clear and convincing evidence, *Microsoft Corp.*, 131 S. Ct. at 2245, it is the *patentee* that "bears the ultimate burden of proof" to "demonstrate infringement by a preponderance of the evidence." *Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665, 679 (Fed. Cir. 2008); *see also Lehigh Valley R.R. Co. v. Mellon*, 104 U.S. 112, 119 (1881) (infringement "cannot be presumed"). A natural application of the Eleventh Circuit's scope-of-the-patent logic would lead to a presumption that the patent was valid but also not infringed. As the leading treatise on IP and antitrust law explains:

> By the same reasoning the Eleventh Circuit used, courts should conclusively presume patents

4. As the Third Circuit observed, "the scope of the patent test does not subject reverse payment agreements to *any* antitrust scrutiny." *K-Dur*, 686 F.3d at 214 (emphasis added). In fact, "no court applying the scope of the patent test has ever permitted a reverse payment antitrust case to go to trial." *Ibid.*

> valid whenever a settlement occurs, but must for the same reason conclusively presume that those patents were not infringed. And if they are (presumptively) not infringed, any settlement that excludes the generic necessarily "exceeds the scope" of "the exclusionary potential of the patent." That would be an irrational result, but so is conclusively presuming that a patent is valid. In both cases, the error lies in substituting a conclusive presumption for the actual evidence before the court.

1 *Herbert Hovenkamp et al.*, IP and Antitrust § 15.3a1, at 15-41 (2012 Supp.).[5]

E. Exclusion Payments Themselves Provide Evidence That the Patent Is Invalid

Exclusion payments are not merely anticompetitive because they exclude competition with potentially invalid patents. They also provide strong evidence that a patent could be found invalid if tested in court.

If a patent is invalid, the patentee has no justification whatsoever for paying the generic one cent to delay competition one day. That is market division. In these

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5. As it happens, in this case, there was substantial evidence that the generics did not infringe Solvay's patent. The patent (mistakenly) covered gel with 1% sodium hydroxide, which "any skilled chemist" knew would "burn a patient's skin." *In re Androgel Antitrust Litigation*, 687 F. Supp. 2d 1371, 1380 (N.D. Ga. 2010). There was evidence—enough to survive a motion to dismiss—that the generic version did not infringe since it contained a diluted solution that was "50 to 250 times less concentrated." *Ibid.*

cases, it is not the patent that "cripple[s] competition," *Schering-Plough v. Federal Trade Comm'n*, 402 F.3d 1056, 1065-1066 (11th Cir. 2005), but the additional payment that immunizes the patent from challenge.

The court below worried about relitigation of the very patent dispute the parties settled. That is a difficult inquiry to undertake, particularly because the parties with the best evidence bearing on the issue have entered into the exclusion-payment settlement and now have incentives to claim that the patent would have been held valid and infringed.

Fortunately, there is another, more reliable source of evidence on the validity of the patent in question. Large exclusion payments (greater than avoided litigation costs) themselves provide powerful evidence that *at the time of settlement*, the parties themselves believed the patent was likely to be invalid or not infringed. At the extreme, a sufficiently large payment should cause a generic to drop even challenges it would surely win. Even in adopting a very deferential scope-of-the-patent test, the Second Circuit in *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187, 206, 208 (2d Cir. 2006) was "suspicious" when a patentee settles litigation by paying "more than either party anticipates the [generic] would earn by winning the lawsuit and entering the . . . market in competition with the patent holder."[6]

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6. It is the relationship to expected generic profits, not patentee profits, that matters here. Patentees will always have an incentive to pay to delay a challenge. If the payment is large enough, generics will no longer have any incentive to litigate, no matter how weak the patent.

The court of appeals' decision to reject the FTC's complaint on a motion to dismiss precluded the development of a full evidentiary record. Even so, the FTC's allegations strongly suggest that the parties thought the patent was on shaky ground. Solvay stood to lose $125 million per year in profits (from its top-selling product) if it lost the case. 677 F.3d at 1305; Complaint ¶ 2. Generics would have priced their drugs at no more than 25% of Solvay's price, *id.* ¶¶ 50-51, meaning that unless they could expand the market dramatically (which was unlikely, Gautier Duflos & Frank R. Lichtenberg, *Does Competition Stimulate Drug Utilization*, 32 Int'l Rev. L. & Econ. 95, 106–07 (2012)), the most they could be expected to make in profits each year would be $31.25 million, and it likely would be far less.[7] Under the settlement, Solvay paid the generics between $29 million and $42 million per year to stay off the market, meaning that the payment at least approached the amount the generics would have made even if they were completely sure they could enter the market. 677 F.3d at 1305. Payments of such large sums offer powerful evidence that the patentee thought the patent was weak indeed.

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7. We cannot determine the exact number because the district court did not allow development of the record. If the market for drugs were elastic—that is, if many patients would buy drugs only at a low price—dropping the price might produce more than $31.25 million in profits. But that's unlikely for a prescription drug like AndroGel® that is a controlled substance whose distribution is restricted by the government. Further, the marginal cost to manufacture a particular dose is unlikely to vary much from maker to maker. So it is quite likely that if anything the generic profit estimate in the text is too high; generics would face the same marginal costs as Solvay but would charge a much lower price.

IV. EXCLUSION PAYMENTS ARE NOT NEEDED TO SETTLE CASES IN THE PUBLIC INTEREST

Courts that have deferred to exclusion-payment settlements have done so in part because of a judicial policy in favor of settlement of disputes. The court below emphasized that "[t]he general policy of the law is to favor the settlement of litigation" and that "patent litigation is costly and complex." *Watson*, 677 F.3d at 1310-11 (citing *Schering-Plough*, 402 F.3d at 1072-74). Similarly, the court found that the agreements in its earlier *Schering* case reflected a "high-stakes reality" and "fell well within the protections" of the patent." *Watson*, 677 F.3d at 1311 (citing 402 F.3d at 1076). In fact, however, this particular form of settlement is unnecessary, undesirable, and at odds with the Hatch-Waxman Act.

1. Not all settlements are desirable. The general preference for settlement over litigation must be tempered when settlements have important adverse effects on third parties; in the language of economics, there is no good reason to encourage settlements that impose significant negative externalities. *See* Louis Kaplow, *The Patent-Antitrust Intersection: A Reappraisal*, 97 Harv. L. Rev. 1813, 1867-73 (1984). Patent litigation serves the crucial role of testing weak patents and protecting the public from monopolies based on invalid patents. This benefit is particularly important in the context of the Hatch-Waxman Act, which exhibits a congressional desire to encourage generic drug manufacturers to challenge pharmaceutical patents.

Drug patent settlements with exclusion payments are not typical settlements. They are agreements that dispose

of the validity and infringement challenges central to the Hatch-Waxman scheme. Any general preference in the law for settlement was displaced—or at least significantly weakened—by the Act's specific framework.

A 180-day period of exclusivity for the first generic to challenge a patent only makes sense in the context of encouraging patent challenges. The period applies only to generics that seek to enter before the end of the patent term. It does not apply to challenges that target expired patents or delay approval until the end of the patent term. A successful patent challenge provides valuable (and in the case of medicines necessary) benefits to third parties, including consumers and anyone who seeks to practice the patented technology.[8]

In addition, the 180-day bounty itself demonstrates the unique nature of these agreements. That provision makes clear that settlements in this context are far more worrisome than general patent settlements. General patent settlements do not prevent other competitors from entering the market. In cases outside the Hatch-Waxman context, even if the settling defendant agrees not to challenge the patent, others are free to enter.

The Hatch-Waxman context is different. It is most definitely not the case, as the court below believed, that "many potential challengers . . . attack[]" vulnerable

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8. *See, e.g.*, Joseph Farrell & Robert Merges, *Incentives to Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help*, 19 Berkeley Tech. L.J. 943 (2004); Joseph Scott Miller, *Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents*, 19 Berkeley Tech. L.J. 667 (2004).

patents because they "are not bound by the first challenger's" settlement and they "will attempt to enter the market." *Watson*, 677 F.3d at 1315. Nor is it the case that a patentee's profits "will be eaten away" as "more and more" generics file paragraph IV certifications. *Ibid.* To the contrary, and alone among all categories of patent settlements, the Hatch-Waxman Act blocks alleged infringers from entering the market until the first Paragraph-IV filer enjoys 180 days of marketing exclusivity. This period does not even begin until the first filer enters the market, potentially years down the road.[9]

An Act intended to increase generic entry should not be perverted into a tool to bar that entry by the mere invocation of a general policy in favor of settlement.

2. Fortunately, exclusion payments are not needed to settle cases. Pharmaceutical patent owners and generic firms can and do settle patent cases without exclusion payments. Several options are available to brand firms: (1) agree to let generics enter upon payment of a license fee, (2) agree with generics, based on the strength of the

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9. The Medicare Modernization Act of 2003 created various forfeiture events that resulted in generics forfeiting their 180-day exclusivity period. But a careful reading of the statute shows that these "use it or lose it" provisions do not trigger forfeiture as quickly as might be assumed. Simplifying greatly, the statute provides that the first filer loses exclusivity if it fails to market the drug by the later of (1) 75 days after FDA approval and (2) 75 days after an appellate court decision finding invalidity or non-infringement. 21 U.S.C. § 355(j)(5)(D)(i). Appellate court decisions typically will not occur until years in the future. While the first filer in this case waived its 180-day exclusivity, the legal rule announced by the court below would also shelter settling parties that do not.

patent alone (not supplemented by exclusion payments), on a time of entry, or (3) take other actions that do not involve paying the generic to forego competition. *See* 1 Herbert Hovenkamp et al., *IP and Antitrust* §15.3a1[C] (2d ed. 2010) ("the *ex ante* effect of a harsh rule will not necessarily impede settlement; it may simply make the settlement take on a different form"). The treatise authors endorse settlements of various forms that do not involve payment for delay.

Indeed, empirical evidence makes it clear that abolishing exclusion payments does not prevent settlement. In 2000, the FTC announced that it would challenge exclusion-payment settlements. Statement of Chairman Robert Pitofsky and Commissioners Sheila F. Anthony, Mozelle W. Thompson, Orson Swindle, and Thomas B. Leary, 65 Fed. Reg. 17506 (April 3, 2000), http://www.ftc.gov/os/2000/03/hoeschtandrxcommstmt.htm. In the succeeding four years, between 2000 and 2004, *not one* of twenty reported agreements involved a brand firm paying a generic filer to delay entering the market. Bureau of Competition, FTC, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005*, at 4 (2006), http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf.

During this period, parties continued settling their disputes, but in ways less restrictive of competition, such as through licenses allowing early generic entry. Indeed, the FTC Report identified 14 such settlements without exclusion payments in 2003-2004 alone. *See id. at* 4. The fact that drug companies can and do settle litigation

without exclusion payments shows that there is no need to tolerate these anticompetitive payments. As was recently shown, an exclusion payment "that exceeds the patent holder's anticipated litigation costs is never necessary to secure a *desirable* settlement." Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, 91 Tex. L. Rev. 283, 303 (2012) [Elhauge & Krueger, *Solving Settlement Puzzle*] (emphasis in original).

V. THIS COURT SHOULD ADOPT A "QUICK LOOK" ANALYSIS THAT PRESUMES THAT EXCLUSION-PAYMENT SETTLEMENTS ARE ILLEGAL

Given the potentially severe anticompetitive effects of exclusion-payment settlements, the appropriate analysis is not the deferential standard applied by the Eleventh Circuit.

A. The Overwhelming Consensus of Scholars Rejects the Eleventh Circuit's Test

Academic commentators have offered different standards for exclusion-payment settlements. But they uniformly agree that such agreements should not be considered per se legal. Some, including some of the undersigned, have written that settlements involving a payment from the patent holder to the challenger that exceeds avoided litigation costs should be presumptively anticompetitive.[10] Others have argued for applying the rule

10. *See, e.g.*, 1 Herbert Hovenkamp et al., *IP and Antitrust* §15.3a1(C) (2d ed. 2010); Robin Cooper Feldman, *The Role of Science in Law* 167 (2009); Jeremy Bulow, *The Gaming*

of reason.[11] Others have advocated per se illegality.[12] But *none* has taken the position adopted by the court below in this case—that the court can just assume the patent is valid and the brand can prevent validity from being tested by paying the generic millions of dollars.

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of Pharmaceutical Patents, in 4 *Innovation Policy and the Economy* (Adam B. Jaffe et al. eds. 2004); Carrier, *Unsettling Drug Settlements*; Tom Cotter, *Antitrust Implications of Patent Settlements Involving Reverse Payments*, 71 Antitrust L. J. 1069 (2004); Elhauge & Krueger, *Solving Settlement Puzzle*; Joseph Farrell & Carl Shapiro, *How Strong Are Weak Patents?*, 98 Am. Econ. Rev. (2008); Hemphill, *Paying for Delay*; Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719 (2003); Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. Econ. Persp. 75 (2005); Rudolph J.R. Peritz, *Three Statutory Regimes at Impasse*, in *More Common Ground for International Competition Law?* (Josef Drexl et al. eds. 2010); Catherine J.K. Sandoval, *Pharmaceutical Reverse Payment Settlements*, 26 Santa Clara Comp. & High Tech. L.J. 141 (2009); Shapiro, *Antitrust Limits*.

11. Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 Fla. L. Rev. 747 (2002); Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, 47 Antitrust Bull. 491 (2002); David W. Opderbeck, *Rational Antitrust Policy and Reverse Payment Settlements in Hatch-Waxman Patent Litigation*, 98 Geo. L.J. 1303 (2010).

12. Maureen A. O'Rourke & Joseph F. Brodley, *An Incentives Approach to Patent Settlements*, 87 Minn. L. Rev. 1767 (2003); Joshua P. Davis, *Applying Litigation Economics to Patent Settlements: Why Reverse Payments Should Be Per Se Illegal*, 41 Rutgers L.J. 255 (2009).

B. A Quick-Look Framework is Appropriate in Analyzing Exclusion-Payment Settlements

1. The relevant antitrust framework that courts apply to business activity is based on an assessment of the likelihood and magnitude of anticompetitive effects and procompetitive justifications.

The problem with the framework adopted by the court below is that it sweeps all anticompetitive issues under the "patent scope" rug and essentially concludes that, as a matter of law, exclusion-payment settlements are per se legal. Under this approach, the issuance alone of a patent (often by an overworked patent examiner) demonstrates its validity and infringement. Even worse, brands can pay generics any amount of money they wish from their newly-guaranteed stream of monopoly profits to make sure this assumption is never tested in court.

That cannot be right. For if the patent would not hold up in court or is not infringed (as evidence has shown applies to many patents), the parties are nakedly dividing markets. And if market division were ever justified, it is certainly not the case in this setting, with consumers paying billions of dollars extra a year and forgoing access to prescription medications.

A full-blown application of the rule of reason also is not appropriate. This is not a garden-variety business arrangement bursting with procompetitive justifications. It is a private settlement that eliminates challenges to patents central to the patent regime and Hatch-Waxman Act.

2. The most appropriate framework for analysis would recognize the anticompetitive concerns with exclusion-payment settlements while giving the settling parties an opportunity to show that they have legitimate justifications that outweigh any anticompetitive effects. That approach could take the form of a quick-look analysis that treats exclusion payments as presumptively unlawful.

This Court has recognized that certain agreements threaten significant anticompetitive harm but also might be justified. In *National Society of Professional Engineers v. United States*, 435 U.S. 679, 692 (1978), this Court found that "no elaborate industry analysis" was needed to "demonstrate the anticompetitive character" of a ban on competitive bidding among members of a professional association. In *Federal Trade Commission v. Indiana Federation of Dentists*, 476 U.S. 447, 459 (1986), the Court did not engage in a full-blown market analysis before finding that a dental association's refusal to submit x-rays to insurers was anticompetitive. And in *National Collegiate Athletic Association v. Board of Regents of University of Oklahoma*, 468 U.S. 85, 113 (1984), the Court placed on the defendant a "heavy burden of establishing an affirmative defense" since a plan for televising college football games "on its face constitute[d] a restraint upon the operation of a free market" and "operated to raise prices and reduce output."

Exclusion payments "represent a significant threat to competition," which "mak[es] a full rule of reason inquiry unnecessary." XII Hovenkamp, *Antitrust Law* ¶ 2046c3, at 350-51 (3d ed. 2012). The "size of the payment" is "a strong indicator of power" since "[a] firm pricing at marginal cost cannot afford to pay large sums to others

to stay out of its market." *Ibid.* ¶ 2046c3, at 351. Settling companies are entitled to offer evidence showing that their settlement is procompetitive, but absent such evidence, an exclusion-payment settlement should be presumed illegal.

3. This approach was applied by the Third Circuit in *K-Dur*. That court articulated a "quick look rule of reason analysis based on the economic realities of the reverse payment settlement." 686 F.3d at 218. In particular, "the finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade." *Ibid.*

The presumption in *K-Dur* "could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit." *Ibid.* The court supported this analysis by pointing to "a long line of Supreme Court cases recognizing that valid patents are a limited exception to a general rule of the free exploitation of ideas" and that "the public interest supports judicial testing and elimination of weak patents." *Ibid.* Notably, however, the *K-Dur* presumption cannot be rebutted simply by arguing that exclusion payments are procompetitive.

The *K-Dur* approach properly applies this Court's quick-look precedents to exclusion-payment settlements. And it identifies potential circumstances in which a payment might not have its normal anticompetitive effect. Others have suggested that a payment limited to the actual cost of litigation could indicate a settlement motivated by cost-avoidance rather than the elimination of competition. 1 Herbert Hovenkamp et al., *IP and Antitrust* § 15.3a1[C],

at 15-52 (2d ed. 2010); Carrier, *Unsettling Settlements*, at 76-77; Elhauge & Krueger, Solving Settlement Puzzle, at 329; Shapiro, *Antitrust Limits*, at 408. A settlement payment limited to litigation costs need not delay entry; a larger payment necessarily delays the expected date of generic entry.

A quick-look analysis allows courts to consider the potentially severe anticompetitive effects of exclusion-payment settlements while permitting the settling parties to introduce possible procompetitive justifications, if any, for their agreement. The court below erred by ignoring these considerations.

CONCLUSION

For the reasons above, this court should reverse the decision of the court below affirming the district court's grant of defendants' motion to dismiss.

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AMICUS CURIAE BRIEF

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Supreme Court of the United States

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Petitioner,

v.

ACTAVIS, INC., ET AL.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Eleventh Circuit

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STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

Amici curiae David W. Opderbeck and Erik Lillquist are Professors of Law at Seton Hall University Law School and are Directors of The Gibbons Institute of Law, Science & Technology, an academic center located within Seton Hall University Law School in Newark, New Jersey. The Gibbons Institute provides a forum for lawyers, judges, scientists, and government officials to discuss the legal, political and social problems that will continue to arise as scientific and technological changes challenge our existing laws and legal institutions. Professors Opderbeck and Lillquist have published and/or taught and lectured in the area of pharmaceutical patent and antitrust law and are interested in the proper interpretation and enforcement of the antitrust laws with respect to pharmaceutical products.

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[1] No counsel for a party authored this brief in whole or in part and no party of counsel for a party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than amici curiae or its counsel made a monetary contribution to its preparation or submission. Counsel of record for all parties received notice of the amici curia's intention to file this brief. The parties have all either filed blanket waivers with the Court or have explicitly consented to the filing of this brief.

SUMMARY OF ARGUMENT

The FTC's proposed "quick look" approach is inadequate because it passes over a fundamentally important consideration: product market definition. Product market definition is basic to antitrust analysis under the rule of reason. Antitrust analysis of restraints such as license agreements involving patents routinely requires product market definition. The Court held in *Illinois Tool Works Inc. v. Independent Ink, Inc.*, 547 U.S. 28, 126 S.Ct. 1281, 164 L.Ed.2d 26 (2006), that a finding that a tying arrangement involving a patent is unlawful "must be supported by proof of power in the relevant market rather than by a mere presumption thereof." *Id.* at 43. The same should be true for reverse payment settlements. Pharmaceutical product markets are complex and often are not delimited by an individual molecule, making a "quick look" inadequate.

ARGUMENT

I. PRODUCT MARKET DEFINITION IS AN INDISPENSABLE STEP IN THE ANTITRUST EVALUATION OF REVERSE PAYMENT SETTLEMENTS

The FTC's proposed "quick look" approach passes over a fundamentally important consideration: product market definition. This is surprising, because a patent's impact on market concentration is a key determinant of the patent's power. *See* David W. Opderbeck, *Rational Competition Policy and Reverse Payment Settlements in Hatch-Waxman Patent Litigation*, 98 GEO. L.J. 1303 (2010).

Product market definition is fundamental to antitrust analysis under the rule of reason. As one leading treatise notes, "[t]he determination of the relevant market is inextricably related to the question of whether the defendant's competitors have been or will be foreclosed from the market by virtue of the challenged acts." CALLMAN ON UNFAIR COMPETITION § 4:31. Only in the context of *per se* liability, or in the case of a "quick look," where the conduct is deemed inherently anticompetitive, is the question of market definition set aside. The FTC and *amici* that seek some kind of *per se* or "quick look" rule concerning reverse payment settlements do not explain why such agreements are inherently anticompetitive, except in a circular fashion that inevitably points back to the need for product market definition.

All of the authorities agree that valid patents provide a legitimate zone of exclusion. The *scope* of a patent's legitimate exclusionary zone is defined by the scope of the claims. The *power* of a patent's legitimate exclusionary zone, however, cannot be defined without reference to product market definition. *See, e.g., Illinois Tool Works Inc. v. Independent Ink, Inc.*, 547 U.S. 28, 126 S.Ct. 1281, 164 L.Ed.2d 26 (2006). The definition of a patent's exclusionary zone must encompass both scope and power.

Scope and power are complementary, but not identical, concepts. It is true that scope and power usually involve a proportional relationship: as the scope of a patent's claims expands, its potential market power expands. A patent claim for "pharmaceutical compounds to treat depression" obviously would confer greater market power than a patent claim for the chemical formulation of *fluoxetine hydrochloride*.[2] The doctrines that limit claim scope – novelty, non-obviousness, and the rules regarding claim construction and the range of equivalents – therefore also serve to constrain patent power. But these doctrines do not fully circumscribe the range of a patent's power. If fluoxetine hydrochloride is the only compound capable of treating depression, a patent claiming that

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[2] Fluoxetine hydrochloride is the generic name for a selective serotonin reuptake inhibitor originally sold under the brand name PROZAC. See Eli Lilly and Company Prozac.com website, available at http://www.nlm.nih.gov/medlineplus/druginfo/meds/a689006.html (last visited February 24, 2013).

compound obviously confers greater market power than is the case when there are multiple non-infringing compounds that can be used to treat depression with similar clinical results.

A response to this view might be that *any* agreement that arguably expands a patent's power should be considered an unlawful restraint of trade. This closely resembles the argument over tying arrangements involving patents, which recently was resolved by the Supreme Court in *Illinois Tool Works*, 547 U.S. 28, 126 S.Ct. 1281, 164 L.Ed.2d 26 (2006).

In *Illinois Tool Works*, the Court reversed a line of precedent holding that tying arrangements involving the tie of patented and unpatented products are *per se* unlawful. According to the Court, the conclusion that a particular tying arrangement involving a patent is unlawful "must be supported by proof of power in the relevant market rather than by a mere presumption thereof." *Id.* at 43. The Court based this conclusion, in part, on Congress' distinction between patent rights and market power in the Patent Act.

The *Illinois Tool Works* Court essentially adopted Justice O'Connor's reasoning in her concurrence in *Jefferson Parish Hospital v. Hyde*, 466 U.S. 2, 37 n. 7, 104 S.Ct. 1551, 80 L.Ed.2d 2 (1984) (Justice O'Connor concurring), a patent tying case abrogated by *Illinois Toolworks*. Justice O'Connor there stated that

> A common misconception has been that a patent or copyright, a high market share, or a unique product that competitors are not able to offer suffice to demonstrate market power. While each of these three factors might help to give market power to the seller, it is also possible that a seller in these situations will have no market power: for example, a patent holder has no market power in any relevant sense if there are close substitutes for the patented product. Similarly, a high market share indicates market power only if the market is properly defined to include all reasonable substitutes for the product.

Id. at 37-38; *see also Walker Process Equipment, Inc. v. Food Machinery and Chemical Corp.*, 382 U.S. 172, 177, 86 S.Ct. 347, 350 15 L.Ed.2d 247 (1965)(stating that "[w]ithout a definition of [the relevant market] there is no way to measure [the patent holder's] ability to lessen or destroy competition."). Neither the nominal nor adjudicated scope of a patent can in themselves define the relevant product market.

Justice O'Connor's reasoning is consistent with antitrust policy concerning intellectual property generally, including the Federal Trade Commission and Department of Justice guidelines for intellectual property licenses. *See* DOJ / FTC ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY, April 6, 1995. A reverse payment

settlement is not, of course, merely a license agreement. However, the antitrust concern over reverse payment settlements is the same as the concern over exclusive licenses: will the agreement result in an unacceptable degree of market concentration? A license agreement can allow the parties to aggregate the legitimate exclusionary power of multiple intellectual property rights in a way that illegitimately concentrates market power. But intellectual property license agreements usually represent an efficient means of allocating rights, without producing excessive product market concentration. Intellectual property licenses therefore are not ordinarily subject to greater or lesser scrutiny under antitrust law than other sorts of transactions allocating property rights. *See id.* § 2.1 (stating that "[a]s with other forms of private property, certain types of conduct with respect to intellectual property may have anticompetitive effects against which the antitrust laws can and do protect. Intellectual property is thus neither particularly free from scrutiny under the antitrust laws, nor particularly suspect under them."). The same should be true of reverse payment settlements.

II. A QUICK LOOK IS INSUFFICIENT BECAUSE MANY, IF NOT MOST, PHARMACEUTICAL PRODUCT MARKETS ARE NEITHER MONOPOLIES NOR DUOPOLIES

Some scholars who have attempted to model the effects of reverse payment settlements have recognized the need for objective measurement of product market concentration. *See, e.g.,* Carl Shapiro, *Antitrust Limits,* 34 RAND J. OF ECON. at

402-04 (2003); Opderbeck, *Rational Antitrust Policy*, 98 GEO. L.J. 1303 (2010). As noted, this is consistent with the way in which enforcement agencies currently evaluate exclusive intellectual property licenses.

Most existing economic models of reverse payment settlements, however, assume only duopoly competition if the settlement is not consummated and the patent is held valid but not infringed. *See* Jeremy Bulow, *The Gaming of Pharmaceutical Patents*, in Adam B. Jaffe, Josh Lerner, and Scott Stern, eds., INNOVATION POLICY AND THE ECONOMY (MIT Press 2004), at 160 (modeling "monopoly days, triopoly days, and duopoly days" resulting from paragraph IV ligation settlements); Robert D. Willig and John P. Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, 2004 THE ANTITRUST BULLETIN 655, 656 (2004) (recognizing that the patent holder might not have monopoly power in real markets but adopting assumption of market power to simplify modeling). This assumption is unrealistic in many pharmaceutical product markets.

In antitrust cases, the relevant market "is composed of products that have reasonable interchangeability for the purpose for which they are produced – price, use and qualities considered." *U.S. v. E.I. Dupont Nemours Co.*, 351 U.S. 377, 404, 76 S.Ct. 994, 100 L. Ed. 1264 (1956). The joint DOJ FTC Merger Guidelines indicate that a product market can be defined by examining whether buyers likely would shift to a substitute product in response to a "small but significant nontransitory increase in

price" – in other words, by the cross-price elasticity of demand. DOJ / FTC MERGER GUIDELINES (April 2, 1992), § 1.1. For pharmaceutical products, "the only logical place from which to determine the relevant product market is from the array of therapeutically substitutable choices available to the doctor." *In the Matter of Schering-Plough Corp.*, FTC Docket No. 9297, Initial Decision, June 27, 2002, at 88.

Expert testimony from physicians, pharmacists, third party payors, and other sources can help establish which products are therapeutic substitutes. It also is possible to quantify the cross-price elasticity of demand for branded and generic products in the same therapeutic class. *See* Sara Fisher Ellison, Iain Cockburn, Zvi Grilliches and Jerry Hausman, *Characteristics of Demand for Pharmaceutical Products: an Examination of Four Cephalosporins*, 28 RAND JOURNAL OF ECONOMICS 426 (1997) (examining cross-price elasticities of cehpalosporins, in a product market that included four different branded compounds); s*ee also* Patricia Danzon and Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets*, 63 JOURNAL OF LAW & ECONOMICS 311, 312 (2000) (noting that "patent-protected drugs may face competition from 'therapeutic substitutes' – drugs with different active ingredients but similar therapeutic effects.").

It is simply not the case that a single molecule necessarily defines a pharmaceutical product market. Often, a significant variety of competing patented and generic products exist in the same class to treat the same condition. For example, at least

five variations of selective serotonin reuptake inhibitors have been approved by the FDA to treat depression.[3] These are sold under at least seven brand names by four different branded manufacturers. *See* Haiden A. Huskamp, et al., *Generic Entry, Reformulations and Promotion of SSRIs in the US*, 26 PHARMACOECONOMICS 603, 604 (2008) (noting that branded SSRIs include PROZAC, PAXIL, ZOLOFT, CELEXA, PAXIL CR, PROZAC WEEKLY, and LEXAPRO). Four of the patents relating to these compounds have expired, and generic versions of these drugs are sold by generic manufacturers. *See id.* In such a product market, the loss of generic competition with respect to one compound would not result in a monopoly, nor would the presence of generic competition with respect to one patent result in a duopoly. In other words, the scope of the patent claims for any one compound does not define the boundaries of the relevant product market.

The definition of a product market for pharmaceuticals, to be sure, is complicated by the need for therapeutic fit between a given compound within a drug class and the patient. It is quite possible, for example, that a patient suffering from depression might respond only to one particular compound within the class of SSRI's. Moreover, some patients being treated with certain types of

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[3] These include citralopram, escitralopram, fluoxetine, paroxetine, and sertraline. See Mayoclinic.com entry for SSRI's, available at http://www.mayoclinic.com/health/ssris/MH00066 (last visited February 22, 2013).

drugs – including psychiatric drugs – report better results from the branded version of a particular compound than from a generic, even though the FDA has found the products to be bioequivalent. Whether this is due to a placebo effect or to some subtleties of the formulation process is unclear. *See, e.g.*, Giuseppe Borgherini, *The Bioequivalence and Therapeutic Efficacy of Generic Versus Brand-Name Psychoactive Drugs*, 25 CLINICAL THERAPEUTICS 1578 (2003). Thus, for any given patient, the product market might not be as broad as the total range of potential treatments.

Even with this caveat, however, it seems reasonable to reject the assumption that all pharmaceutical product markets in which a paragraph IV validity challenge has been mounted to a patent are either only potential monopolies or duopolies. Therefore, at least as a first rough measure of competitive effect, it is reasonable to define the relevant product market to include all potentially competing drugs in the same class. An objective measure of product market concentration, such as the commonly used Herfindahl-Hirschman Index ("HHI"), could readily be employed "[a]s an aid to the interpretation of [this] market data." DOJ / FTC HORIZONTAL MERGER GUIDELINES, § 1.5. This measure of product concentration could be employed together with an approximate assessment of patent strength to establish an index for gauging the likely competitive effects of a reverse payment settlement in a particular market. *See* Opderbeck, *Rational Competition Policy*, 98 GEO. L.J. 1303. In any event, reverse payment settlements should not be declared *per se* or presumptively illegal. Product market

analysis is essential to antitrust review of most restraints of trade, including most restraints involving patents. *See Illinois Tool Works*, 547 U.S. 28, 126 S.Ct. 1281, 164 L.Ed.2d 26.

III. CONCLUSION

The FTC's proposed presumptive illegality approach to evaluating reverse payment settlements should be rejected because it fails to consider the importance of product market definition.

Respectfully submitted,

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AMICUS CURIAE BRIEF

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v.

ACTAVIS, INC., ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

BRIEF OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PHRMA) AS AMICUS CURIAE IN SUPPORT OF RESPONDENTS

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INTEREST OF AMICUS[1]

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA's mission is to advocate in support of public policies that encourage the discovery of life-saving and life-enhancing new medicines. During 2011 alone, PhRMA members invested an estimated $49.5 billion in discovering and developing new medicines, and they have invested more than $500 billion since 2000.[2] PhRMA closely monitors pertinent legal issues and has frequently participated in cases before this Court.

The question presented in this case—whether innovator companies can lawfully settle Hatch-Waxman patent litigation on terms that do not affect competition beyond the exclusionary scope of the patent and that also include some form of consideration flowing to the alleged infringer—is of critical importance to the

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[1] The Federal Trade Commission (FTC) has consented to the filing of amicus curiae briefs in support of either party or of neither party, in a letter on file with the Clerk. Counsel for each of the respondents consented to the filing of this brief pursuant to Rule 37.3(a). No counsel for any party authored this brief in whole or in part, and no person or entity, other than amici curiae or their counsel, made a monetary contribution intended to fund the preparation or submission of this brief. A list of PhRMA's member companies resides at www.phrma.org/about/member-companies (last visited Feb. 27, 2013). PhRMA's members include AbbVie, Inc., which is the parent company of respondent Solvay. AbbVie neither participated in PhRMA's preparation of the brief, nor made a monetary contribution intended to fund the brief's preparation.

[2] See PhRMA, *Pharmaceutical Industry 2012 Profile* 28 fig. 10 (2012), http://www.phrma.org/sites/default/files/159/phrma_industry_profile.pdf (last visited Feb. 27, 2013).

pharmaceutical industry. In order to continue the extraordinary investments in research and development necessary to offer new life-saving and life-enhancing treatments, innovators must have the option of reasonably settling the proliferation of Hatch-Waxman litigation that almost inevitably follows introduction of a new pharmaceutical.

SUMMARY OF THE ARGUMENT

The stakes at issue for innovator companies in Hatch-Waxman Act patent litigation are immense. The cost of developing and obtaining the FDA's approval of a new medicine can total well over a billion dollars. Patent protection is essential to encouraging and potentially recouping that investment as well as funding future research into new medicines. The cycle of successful medicines funding the next generation of breakthroughs is a quintessential example of the Framers' idea that patents should "promote the Progress of Science and useful Arts." U.S. Const. art. I, § 8. Yet patent litigation is notoriously unpredictable, and the innovator faces a rapid loss of sales within a few months of generic entry into the marketplace. Under these circumstances, an innovator could reasonably prefer to achieve certainty through compromise rather than litigate to final judgment, even if it firmly believes that the patent at issue is valid and infringed by generic applicants.

Flexibility in resolving Hatch-Waxman litigation becomes even more important when one considers that the structure of the Act puts patents at risk while minimizing risk to the generic challengers. The Act creates a framework for the litigation of patent disputes under which litigation begins prior to generic entry. Thus, unlike the typical (non-Hatch-Waxman) patent litiga-

tion, alleged infringers can force innovators to defend their patents without incurring any exposure to actual damages from marketing the potentially infringing product. Those suits create uncertainty, which both the innovator and generic challenger have an interest in managing.

The asymmetric character of the risks naturally affects the parties' negotiations. Because the generic typically has no damages liability to forgive, that common form of consideration to an infringer in non-Hatch-Waxman patent litigation is usually unavailable. Instead, Hatch-Waxman settlements can result in some other form of consideration flowing from the innovator company to the generic, often in addition to the generic being licensed to enter the market and practice the patent commercially before the expiration of its remaining term.

These settlements benefit patients and the public. By protecting the innovator company's investment and funding source for new research, they ensure the continued research and development of new treatments against our most grievous and deadly diseases. In addition, by allowing generic entry prior to the end of the patent terms, these settlements speed the introduction of lower-cost medicines into the market. And they conserve scarce financial and managerial resources that would otherwise be spent on litigation.

Under well-established principles of antitrust and patent law, such settlements are permissible. Indeed, the law strongly favors resolution of litigation through compromise, given the public and private costs of litigation. Until recently, faced with antitrust challenges to such settlements, the courts of appeals united in concluding that the correct expression of the rule of

reason in the case of a Hatch-Waxman settlement is to permit settlements of bona fide, non-sham, non-fraudulent patent litigation if the exclusionary scope of the settlement is no greater than the patent's own reach—*i.e.*, the settlement does not exceed the scope of the patent. This "scope of the patent" test accords with the presumption of validity afforded patents and with the fundamental principle of antitrust law that the challenger must prove, rather than assume, that an alleged restraint eliminates actual or potential competition. The test is readily administrable, reducing the costs of enforcement and potential for erroneously condemning procompetitive settlements.

Blind to the benefits of such settlements, the FTC seeks to impose a rule of presumptive illegality. Such a rule would eviscerate the presumption of patent validity—perversely assuming that a patent must be weak simply because an innovator chose to settle—and relieve the antitrust plaintiff of its burden to demonstrate an impairment of actual or potential competition. It also lacks any foundation in this Court's precedent. The Court applies "quick look" analysis only when the irredeemably anticompetitive nature of a restraint is plain. Such is not the case here, where settlements with consideration flowing to generics foster procompetitive benefits, and the supposed anticompetitive effects rest upon the indefensible assumption that generic challengers in patent infringement litigation will win. The FTC, moreover, proposes an unworkable doctrine: an invitation to post-settlement antitrust litigation as protracted and burdensome as the patent litigation sought to be settled. It would deprive innovator companies of an important tool to manage risk and, instead, force them to fight to judgment. The end

result would not further competition, but instead harm patients by hindering development of new and innovative medicines.

ARGUMENT

I. HATCH-WAXMAN SETTLEMENTS, INCLUDING WHERE CONSIDERATION FLOWS TO THE INFRINGER, PRESERVE THE PATENT LAW'S PROCOMPETITIVE INCENTIVES TO INNOVATE

Hatch-Waxman litigation puts at risk the billion-dollar-plus investment that an innovator company has made in bringing a new medicine to market, as well as the company's ability to fund new technological breakthroughs. As in other contexts, settlements enable the patent holders to manage litigation risk. Such settlements, including where consideration flows to the alleged infringer, foster innovation by producing certainty, conserving resources, and *accelerating* generic entry earlier than the patent's expiration.

Contrary to the FTC's contention that such settlements "depart from usual settlement practices," Pet. Br. 16, and thus are a tell-tale sign of some conspiracy against the public interest, they in fact reflect the ordinary give-and-take inherent in a settlement process. To the extent such settlements differ from settlements in ordinary infringement litigation, those differences reflect the special features of the Hatch-Waxman Act, which establishes a framework in which patent litigation takes place before the alleged infringer has incurred any actual damages. To reach a reasonable settlement, innovators at times must compensate generic challengers for *not* infringing during some or all of the remaining life of the disputed patent. The law favors settlement over litigation, and such Hatch-

Waxman settlements are equally entitled to the benefit of that rule.

A. Hatch-Waxman Settlements Foster Innovation By Allowing Innovators To Maintain The Considerable Investment Needed To Develop Medicines

Hatch-Waxman settlements foster innovation and benefit consumers by mitigating the uncertainty and risk of error associated with patent litigation, vagaries that pose a direct threat to PhRMA member companies' ability to continue making tremendous investments in researching new and better treatments.

Innovator pharmaceutical companies invest, on average, more than a billion dollars for each FDA-approved medicine. Such investment inherently involves a high degree of uncertainty. As even the FTC has acknowledged, for every 5,000 to 10,000 compounds screened in pre-clinical testing, only five reach clinical testing, and only one receives FDA approval. FTC Bureau of Economics, *The Pharmaceutical Industry: A Discussion of Competitive & Antitrust Issues in an Environment of Change* 178 (March 1999) (FTC 1999 Report) http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf (last visited Feb. 27, 2013). The research and development of a new medicine takes an average of 10 to 15 years. PhRMA, *Drug Discovery and Development: Understanding the R&D Process* 1 (2007), http://www.innovation.org/drug_discovery/objects/pdf/RD_Brochure.pdf (last visited Feb. 27, 2013). The estimated cost to develop a pharmaceutical treatment (including the cost of failures) in 2005 was $1.2 billion. J.A. DiMasi & H.G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 Managerial & Decision Econ. 469, 475-476

(2007); J.A. DiMasi *et al.*, *The Price of Innovation, New Estimates of Drug Development Costs*, 22 J. Health Econ. 151, 181-182 (2003). Only two of ten marketed medicines return revenues that match or exceed the average costs of research and development. *Id.* at 16 (citing J.A. Vernon *et al.*, *Drug Development Costs When Financial Risk is Measured Using the Fama-French Three-Factor Model*, 19 Health Econ. Letters 1002-1010 (2010)).

Successful patented products accordingly are vital to innovator companies' financial future and their ability to develop the next generation of life-saving medications. Precisely as the Constitution's Framers envisioned, patents allow innovators to reinvest the revenue streams generated by present inventions into further research endeavors. See U.S. Const. art. I, § 8. Innovator companies are able to undertake costly research with uncertain payoff only because patent protection offers the prospect of recovering that investment during the period of patent exclusivity. "[E]mpirical research indicates that new product development in the pharmaceutical industry is more dependent on patent protection than in many other industries." FTC 1999 Report 180. One study found that 60 percent of inventions within the pharmaceutical industry would not have been developed in the absence of patent protection. *Ibid.* (citing Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 Mgmt. Sci. 173 (1986)); see also Richard C. Levin *et al.*, *Appropriating the Returns from Industrial Research & Development*, 3 Brookings Papers on Econ. Activity 783, 796 (1987) (multi-industry survey finding, *inter alia*, the pharmaceutical industry to be the only one in which product patents were viewed as the

most effective means of obtaining a return on research and development).

Not surprisingly, novel innovations that are successful in the marketplace also attract challenges from would-be generic competitors, and PhRMA's members must manage the enormous risks associated with such litigation. It is precisely when an innovative pharmaceutical is successful that generic firms are most incentivized to challenge the patent—regardless of its perceived strength. See H.G. Grabowski *et al.*, *Evolving Brand-Name and Generic Drug Competition May Warrant a Revision of the Hatch-Waxman Act*, 30 Health Affairs 2157, 2161 (2011) (noting higher probability of Paragraph IV challenge for new drugs with sales greater than $100 million, "increasing from 17 percent in 1995 to 75 percent in 2008"). Indeed, the FTC's own calculations suggest that, based on the large potential upside and negligible downside for a would-be generic challenger, "a rational [g]eneric company would challenge patents on drugs accounting for 90 percent of pharmaceutical sales if it had a likelihood of success *in the low to mid-single digits*." Kelly Smith & Jonathan Gleklen, *Generic Drugmakers Will Challenge Patents Even When They Have a 97% Chance of Losing: The FTC Report that K-Dur Ignored*, CPI Antitrust Chronicle 6 (2012) (emphasis added), https://www.competitionpolicyinternational.com/file/view/6746 (last visited Feb. 27, 2013).

The Hatch-Waxman Act facilitates such patent challenges by establishing a framework under which the innovator's patent's validity and generic's infringement can be litigated without the generic launching a competing product and incurring any significant damages liability. See Pet. Br. 4-6. Such litigation

poses grave risks to innovator companies. Studies have shown that "pharmaceutical companies experienced sharp drops in market value after key patents were held noninfringed or invalid." James Bessen & Michael J. Meurer, *Lessons for Patent Policy from Empirical Research on Patent Litigation*, 9 Lewis & Clark L. Rev. 1, 10 (2005) (citing example of innovator company that "lost nearly 30% of its stock market value" after losing patent challenge).[3]

PhRMA's members accordingly must manage the considerable litigation risk that such suits pose to the revenue stream that rewards past investment and allows reinvestment in further medical advancements. As the court of appeals recognized, patent litigation is an "infamously costly and notoriously unpredictable process." Pet. App. 3a. Regardless of an innovator's own confidence in the strength of a patent, "[n]o one can be *certain* that he will prevail in a patent suit." *Asahi Glass Co.* v. *Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 993 (N.D. Ill. 2003) (Posner, J.). The risk that the factfinder may not understand the technical complexities of modern patents is inherent in any patent

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[3] The importance of patent protection in the pharmaceutical industry is also reflected in the fact that innovators' rewards diminish much more quickly upon patent expiration than in other industries. See Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context & Fidelity to First Principles*, 15 Fed. Cir. Bar J. 617, 624-625 (2006). When a generic version of a medicine first becomes available, it can capture more than 90% of the sales within the very first month. See PhRMA, *Chart Pack: Biopharmaceuticals in Perspective* 41 (2010), http://catalyst.phrma.org/wp-content/uploads/fromPhrma/phrma_chart_pack.pdf (last visited Feb. 27, 2013) (citing Medco Health Solutions, *2009 Drug Trend Report* (2009)).

litigation. And even the district court's own rulings are an uncertain guide to the litigation's ultimate outcome. By one account, "nearly 40 percent of claims constructions are changed or overturned by the Federal Circuit." *TM Patents, L.P.* v. *IBM Corp.*, 72 F. Supp. 2d 370, 378 (S.D.N.Y. 1999). Indeed, Hatch-Waxman litigation can raise questions that even members of the Federal Circuit find difficult to resolve. In *Purdue Pharma L.P.* v. *Endo Pharm. Inc.*, for example, a panel of Federal Circuit judges initially affirmed a ruling in favor of the generic challenger, only to reverse itself on reconsideration eight months later. See 438 F.3d 1123, 1125-1126 (2006).

Faced with such litigation uncertainty, many pharmaceutical innovators quite reasonably choose to settle challenges to their patents, just as patent holders do in the vast majority of cases. Indeed, across all patent cases, 95% are resolved by settlement. Marc G. Schildkraut, *Patent-Splitting Settlements & the Reverse Payment Fallacy*, 71 Antitrust L.J. 1033, 1048 (2004). This high rate of settlement reflects in part the recognition that patentees are likely to suffer irreparable harm if, for example, a generic launches after a favorable district court decision, but the patent is ultimately upheld and found infringed on appeal. Under those circumstances, the brand would never recover its previous position, and a damages award against the generic will not make the innovator whole. For innovators, the prospect of being forced to subject all of their most successful patents to the vagaries of litigation would chill the massive investments they make in developing and marketing life-saving medications.

The ability to settle Hatch-Waxman litigation is thus essential to preserving the incentives to innovate.

Consideration flowing to the generic company, in turn, may be necessary at times to make settlement possible. As in other settlement contexts, parties may have different expectations of the outcome of the suit. Both the innovator and generic may predict victory. A payment to the alleged infringer may be needed to help bridge the gap separating the parties' assessment of the case's merits—and, in the long run, may preserve the incentive to invest in innovation crucial to securing consumer welfare. Or the parties may simply have asymmetric risk profiles. See Schildkraut, *supra*, at 1034 (describing some of the "many circumstances where a reverse payment is necessary to resolve a patent litigation and that resolution is better for consumers than continued litigation"); Bernard & Tom, 15 Fed. Cir. B.J. at 629-631 (further describing these scenarios).

The adverse consequences of deterring innovation by effectively banning these settlements would be severe. Benefits from innovation are far more valuable to consumers than static price competition. See Mark A. Lemley, *A New Balance Between IP & Antitrust*, 13 Sw. J. Law & Trade Am. 237, 248 (2007). To take just one very specific example, since 1980, life expectancy for cancer patients has increased by about 3 years, with 83% of the gains attributable to new treatments, including medicines. E. Sun, *et al.*, *The Determinants of Recent Gains in Cancer Survival: An Analysis of the Surveillance, Epidemiology and End Results (SEER) Database*, 26 J. of Clinical Oncology suppl. 15 (2008). More generally, a National Bureau of Economic Research working paper found that 40% of the increase in longevity from 1986-2000 was due to the launch of new medicines. Frank R. Lichtenberg, *The Impact of New Drug Launches on Longevity: Evidence from Longitu-*

dinal, Disease-Level Data from 52 Countries, 1982-2001, NBER Working Paper No. 9754 (2003), http://www.nber.org/papers/w9754 (last visited Feb. 27, 2013).

Furthermore, contrary to the suggestion of petitioner's amici, see Br. of Public Patent Found. 9-13, multiple generic challengers often attack patents covering the core active ingredient in innovators' medicines—not just the so-called "secondary" patents on improvements to existing medicines denigrated by amici. Very recently, among scores of other such examples, the Federal Circuit upheld the patent for the active ingredient in Crestor against challenges by eight generic pharmaceutical companies. See *In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511 (Fed. Cir. 2012); see also, *e.g.*, *Sanofi-Aventis* v. *Apotex Inc.*, 659 F.3d 1171 (Fed. Cir. 2011) (upholding patent for active ingredient in Plavix); *AstraZeneca Pharm. LP* v. *Teva Pharm. USA, Inc.*, 583 F.3d 766 (Fed. Cir. 2009) (upholding patent for active ingredient in Seroquel against challenges by two generic companies); *Pfizer, Inc.* v. *Teva Pharm. USA, Inc.*, 518 F.3d 1353 (Fed. Cir. 2008) (upholding patent for active ingredient in Celebrex); *Pfizer, Inc.* v. *Teva Pharm. USA, Inc.*, 882 F. Supp. 2d 643 (D. Del. 2012) (upholding patent for active ingredient in Lyrica against challenge by eight generic pharmaceutical companies); *Schering Corp.* v. *Mylan Pharm., Inc.*, No. 09-6383, 2012 WL 1473329 (D.N.J. Apr. 27, 2012) (slip copy) (upholding patent for active ingredient in Zetia and Vytorin); *Pfizer Inc.* v. *Teva Pharm. USA, Inc.*, 803 F. Supp. 2d 409 (E.D. Va. 2011) (upholding patent for active ingredient in Viagra).

In any event, amici's denigration of so-called "secondary" patents is wholly unwarranted, since innovations covered by improvement patents—such as new formulations—also yield significant benefits to consumers. See Int'l Fed'n of Pharm. Mfrs. & Ass'ns (IFPMA), *Incremental Innovation: Adapting to Patient Needs* 8-14 (2013), http://www.ifpma.org/resources/publications.html (last visited Feb. 27, 2013). These innovations benefit consumers by, for example, improving the efficacy of a medicine; eliminating the need for administration by a highly skilled medical professional; reducing or eliminating side effects that deprive some patients of a medicine's benefit; and reducing the required frequency of administration. See, *e.g.*, *id.* at 10-14, 19-22 (describing examples). Such improvements can, in turn, increase patient compliance, thereby preventing treatment failure. *Id.* at 12-13 (discussing, *e.g.*, improved anti-malaria formulation that reduced dosing regimen from 8 tablets per day to 2). If a particular "secondary" patent is said to lack value, the market provides a ready cure, since patents on improvements do not prevent the advent of generic versions of the original product. *Id.* at 17. The market will then decide if the improved product is worth a premium over cheaper generic versions of the original.

B. Settlements With Consideration Flowing To Alleged Infringers Can Accelerate Generic Entry

In addition to preserving the incentive to innovate, Hatch-Waxman settlements, including those with consideration flowing to the alleged infringer, also benefit patients and payers by facilitating entry of generic competitors prior to the expiration of innovators'

patents. This very case provides such an example: Respondent Solvay agreed to allow the respondent generic manufacturers to enter in 2015, five years before the disputed patent for Androgel expires. See Pet. App. 10a, 12a. Patients and payers will thus benefit from five years of generic price competition more than if Solvay had prevailed in invoking its patent to exclude such competition until 2020. Similarly, in the agreements at issue in *Merck & Co.* v. *Louisiana Wholesale Drug Co.* (No. 12-245) (petition pending), the innovator settled on terms that resulted in generic entry five years earlier than the patent's expiration.

There is no basis for the FTC's contention that, but for these settlements, generic entry usually (or even often) would occur earlier. Pet. Br. 28-30. As noted, in some circumstances a settlement that includes some form of consideration flowing to the generic company may be needed to make settlement possible. See p. 11, *supra*. Including consideration to the generic "may allow the brand-name and generic manufacturers to bridge the settlement gap" between them. Bret Dickey *et al.*, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 Annals Health L. 367, 394 (2010). If compromise on such terms is forbidden, more cases will be litigated to conclusion. When the innovator prevails, it will be able to prevent generic entry until the patent's expiration.

The suggestion by the FTC and its amici that, in the absence of settlement, such patent litigations would more likely than not terminate in the generic firms' favor is baseless. The FTC and amici rest their entire argument on a 73% figure that is deeply flawed. See Pet. Br. 6 (citing FTC, *Generic Drug Entry Prior to Patent Expiration* 16 (2002) (FTC 2002 Report),

http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf (last visited Feb. 27, 2013) (claiming a generic success rate of 73%)). The 73% figure is more than a decade old and out of date. More recent data regarding cases litigated to decision indicates that generic challengers prevail less than half the time. See Adam Green & D. Dewey Steadman, *Analyzing Litigation Success Rates*, RBC Capital Markets 4 (Jan. 15, 2010), http://amlawdaily.typepad.com/pharmareport.pdf (last visited Feb. 27, 2013) (finding only 48% generic success rate from 2000-2009 in 171 cases litigated to decision).

Moreover, subsequent developments revealed that the cases the FTC surveyed (from 1992-2000) were skewed based on the very high proportion of cases that settled. A study from immediately after that period reported that, "after FTC and private antitrust actions began to discourage settlement," there was a "significant jump in the number of cases won by innovator companies." Bernard & Tom, 15 Fed. Cir. B.J. at 627-628. In other words, by discouraging settlements, the FTC succeeded in pushing more innovators to litigate cases, which they won, enabling them to prevent generic entry until patent expiration.[4]

Tellingly, many Hatch-Waxman settlements, including settlements that involved payments to the alleged infringer and permitted generic entry prior to the

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[4] Even on its own terms, the FTC's 73% figure is dubious. As of the time of the FTC's report, the generic had prevailed in a final decision with respect to only 22 of 75 products. FTC 2002 Report 10, 14 16. To reach the 73% figure, the FTC disregarded all cases still pending at the time of the survey, all cases that had settled (no matter the settlement's terms), and instances in which the same patent was vindicated multiple times. See *id.* at 16-19.

patent's expiration, have been followed by subsequent patentee victories with respect to the very same patent. In these situations, settlement undoubtedly accelerated generic competition. In the *Ciprofloxacin* case, for example, "despite payments from a patentee to an infringer of more than $400 million, 'the patent was subsequently approved * * * on reexamination and unsuccessfully challenged in court three times.' " Bernard & Tom, 15 Fed. Cir. B.J. at 627 (quoting *Valley Drug Co.* v. *Geneva Pharm., Inc.*, 344 F.3d 1294, 1310 (11th Cir. 2003) (citing *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003))). Litigation over Plavix illustrates the same point: the innovator offered to settle the case, including allowing the generic to enter early and offering consideration in the form of an agreement not to issue an authorized generic; the FTC refused to approve the settlement (pursuant to a court order entered in a different case); and the innovator ultimately prevailed on its infringement claim, obtaining damages for the period during which the generic had launched at risk. See *Sanofi-Aventis*, 659 F.3d at 1174-1177; see also, *e.g.*, *Pozen, Inc.* v. *Par Pharmaceutical, Inc.*, 696 F.3d 1151 (Fed. Cir. 2012) (upholding multiple patents covering Treximet against challenge by three generic companies, after Pozen had settled with fourth); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 193, 195, 204 (2d Cir. 2006) (as amended) (rejecting antitrust challenge to settlement, where patent had subsequently been upheld against three generic challenges), cert. denied, 551 U.S. 1144 (2007). The alternative to settlement on terms involving consideration to the alleged infringer will often be litigation to a judgment favorable to the patentee, thus preventing early generic entry before the patent expires. It is perverse to deter set-

tlements that enable a generic competitor to bring its product to market years before it could if the patent were fully enforced.

C. The Flow of Consideration To Alleged Infringers Is A Natural And Appropriate Result Of The Statutory Scheme

Contrary to the FTC's contention, see Pet. Br. 16, consideration flowing to the alleged infringer is not a sign of an anticompetitive scheme. Such terms are "a natural by-product of the Hatch-Waxman process" designed by Congress. *Schering-Plough Corp.* v. *FTC*, 402 F.3d 1056, 1074 (11th Cir. 2005), cert. denied, 548 U.S. 919 (2006).

In a run-of-the-mill settlement, consideration flows from the plaintiff-innovator to the alleged infringer when, as part of the parties' bargain, the plaintiff-innovator forgoes collecting a portion of the alleged damages. See *Ciprofloxacin*, 261 F. Supp. 2d at 252 (recognizing that "even in the traditional context," "[i]n reality, what has occurred is the alleged infringer is permitted to keep a portion of the profits from its sales"). Because Hatch-Waxman litigation, by Congress's design, commences at the time the Paragraph IV certification is filed (and deemed an act of infringement) but before any damages would be incurred, the usual form of consideration from the patentee to the infringer—declining to collect a portion of the damages—does not yet exist. See Pet. Br. 4-6 (discussing statutory scheme). This structure creates an asymmetry: while the "statutory scheme could then cost [the innovator] its patent," *Schering-Plough*, 402 F.3d at 1074, the would-be generic competitor, faces only "exposure to liability amount[ing] to litigation

costs," *ibid.*, and a delay in the ability to recoup its relatively modest investment in submitting an ANDA.

In this context, a payment (or other compensation) to an alleged generic infringer may at times provide the only reasonable terms on which a settlement can be achieved. See p. 11, *supra*. "Given the asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement." *Valley Drug Co.* v. *Geneva Pharm., Inc.*, 344 F.3d 1294, 1310 (11th Cir. 2003), cert. denied, 543 U.S. 939 (2004); see p. 8, *supra*. It is not surprising, then, that Hatch-Waxman settlements often contain such terms. See FTC Bureau of Compet., *Agreements Filed with the FTC Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003* 2 (2012), http://www.ftc.gov/os/2013/01/130117mmareport.pdf (last visited Feb. 27, 2013) (among all Hatch-Waxman settlements from 2004-2012, according to the FTC, 165 settlements—approximately one quarter—involved compensation flowing to the generic manufacturer).

From the innovator's perspective, providing consideration to the generic company serves the same purpose as agreeing to forgo a portion of the alleged damages in other settlement contexts: to reach a compromise, including conceding some ground to the alleged infringer (including, at times, providing terms that could not be obtained as relief in the litigation), rather than bearing the many burdens and risks entailed in litigating the dispute to its end. See *Asahi Glass*, 289 F. Supp. 2d at 993. For similar reasons, patent settlements outside of the Hatch-Waxman context also often contain consideration flowing to the alleged infringer in the form of a license pertaining to an unasserted pa-

tent, such as one related to the patent-in-suit. Such consideration, though beyond what the infringer could win at trial, may be necessary in the process of getting a deal done. Indeed, "a*ny* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to be classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements." *Id.* at 994. And, just as with other settlements, a settlement in this context that involves consideration flowing to the alleged infringer benefits not only the parties, but also consumers and society.

D. Hatch-Waxman Settlements Conserve Resources

Finally, as do all settlements, Hatch-Waxman settlements in which consideration flows to the generic company reduce the many direct and indirect costs of litigation that innovators, generic manufacturers, and consumers bear. Such costs include the non-negligible time spent by firm employees "preparing the case, producing documents, working with lawyers on litigation strategy, being deposed, traveling for lawsuit-related events, testifying at trial, and observing legal proceedings." Daniel A. Crane, *Ease Over Accuracy in Assessing Patent Settlements*, 88 Minn. L. Rev. 698, 703-704 (2004). Discovery also imposes risks, including loss of control of sensitive competitive information and harm to business relationships. *Id.* at 704.

And on-going litigation may sap an innovator's resources in more subtle ways. For example, "[t]he length of patent litigation may * * * mak[e] marketing, research and development, and other business planning difficult while the outcome of the case remains uncer-

tain." Crane, 88 Minn. L. Rev. 704; see also *Schering-Plough*, 402 F.3d at 1075-1076 (recognizing that "[p]atent litigation breeds a litany of direct and indirect costs"). And, of course, litigation entails social costs in the expenditure of judicial resources overseeing litigation that can take up to a decade, through trial and eventual appeal. See *ibid.* (noting the "public problems associated with overcrowded court dockets").

Because of the considerable savings gained by settlement, the law strongly favors resolution of litigation through compromise. See, *e.g.*, *McDermott, Inc.* v. *AmClyde*, 511 U.S. 202, 215 (1994). These considerations apply with equal force to, and provide yet an additional procompetitive rationale for, Hatch-Waxman settlements.

II. Correct Application Of The Rule Of Reason Through The "Scope Of The Patent" Test Secures These Benefits

A. The "Scope Of The Patent" Test Is The Correct Expression Of The Rule Of Reason In Evaluating Patent Settlements

The "scope of the patent" test employed by the majority of circuits, see *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008) (describing consensus of Second, Eleventh, and Federal Circuits), cert. denied, 557 U.S. 920 (2009), appropriately secures the above-described benefits to consumers. "[T]his Court presumptively applies rule of reason analysis, under which antitrust plaintiffs must demonstrate that a particular contract or combination is in fact unreasonable and anticompetitive before it will be found unlawful." *Texaco Inc.* v. *Dagher*, 547 U.S. 1, 5 (2006); see also *Leegin Creative Leather Prods.* v. *PSKS, Inc.*, 551 U.S. 877, 885-886 (2007),

cert. denied, 131 S. Ct. 1476 (2011). The inquiry under the rule of reason must be appropriate for the type of restraint at issue. *Cal. Dental Ass'n* v. *FTC*, 526 U.S. 756, 781 (1999) (inquiry must be "meet for the case, looking to the circumstances, details, and logic of a restraint"). Accordingly, antitrust courts have long recognized that the correct expression of the rule of reason can consist of a conduct-specific rule applicable to a particular type of conduct. See, *e.g.*, *Brooke Grp. Ltd.* v. *Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 222-224 (1993) (setting rules for low pricing under Section 2).

Here, as explained below, the correct expression of the rule of reason in the context of Hatch-Waxman settlements is the "scope of the patent" test—a test the FTC incorrectly characterizes as a rule that such settlements are "per se lawful." See Pet. Br. I (question presented).

1. The FTC mischaracterizes the "scope of the patent" test

As an initial matter, the "scope of the patent" test does not, as the FTC claims, see Pet. Br. I, render all settlements *per se* lawful. As the FTC itself acknowledges, the scope of the patent test does not protect settlements where the patent was itself obtained by fraud, or where the patent litigation was a sham. *Ibid.*; Pet. App. 28a. As developed and applied by the courts of appeals, the scope of the patent test permits consideration to the alleged infringer *only* in settlements of bona fide, non-sham, non-fraudulent Hatch-Waxman litigation. See, *e.g.*, *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 208 (2d Cir. 2006) (as amended) (recognizing that settlements of sham litigation would be "devices—masks—for fixing prices, in violation of

antitrust law") (quoting *Asahi Glass Co.* v. *Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 991 (N.D. Ill. 2003) (Posner, J.)), cert. denied, 551 U.S. 1144 (2007).

Moreover, under the court of appeals' test, the FTC can still establish liability if it can prove that the settlement in question restricts competition beyond the force of the patent itself. See *Valley Drug Co.* v. *Geneva Pharm., Inc.*, 344 F.3d 1294, 1312 (11th Cir. 2003) (If the settlement strays beyond the patent's scope, those excesses "may then be subject to traditional antitrust analysis to assess their probable anti-competitive effects in order to determine whether [they] violate § 1 of the Sherman Act."), cert. denied, 543 U.S. 939 (2004); see, *e.g.*, *Andrx Pharm., Inc.* v. *Elan Corp.*, 421 F.3d 1227, 1235 (11th Cir. 2005) (plaintiff stated claim where settlement terms allegedly precluded post-expiration generic entry). In other words, the court of appeals' test does not categorically bless all Hatch-Waxman settlements. Rather, it puts the burden where it belongs, on the party challenging the settlement as violating the antitrust laws.

2. The "scope of the patent" test is the correct expression of the rule of reason

The "scope of the patent" test is the correct expression of the rule of reason because it accords with basic principles of antitrust law in the patent context: (i) the law does not protect supposed "competition" via infringement of patents that are presumptively valid; (ii) antitrust rules must take into account long-run effects on competition and consumers; and (iii) readily administrable rules, like the scope of the patent test, best secure procompetitive benefits for consumers. By

contrast, the FTC's unwarranted rule violates each of these precepts.

(i) To begin with, the scope of the patent test—by permitting innovators to restrict competition within, but only within, the scope of the patent—recognizes that the law does not protect "competition" in the form of patent infringement, and that it is improper to circumvent this fundamental principle by assuming the patentee will lose its suit.

A settlement of litigation implicates the antitrust laws only if the two firms are indeed actual or potential competitors; otherwise, no competition is restrained. See *United States* v. *MMR Corp.*, 907 F.2d 489, 498 (5th Cir. 1990) ("[A]n agreement not to compete between two parties who are not actual or potential competitors is not per se or otherwise illegal.") (collecting cases), cert. denied, 499 U.S. 936 (1991); accord *United States* v. *Sargent Elec. Co.*, 785 F.2d 1123, 1127 (3d Cir. 1986) (noting that antitrust courts have recognized in numerous contexts that "[a]n agreement among persons who are not actual or potential competitors in a relevant market is for Sherman Act purposes *brutum fulmen*"), cert. denied, 479 U.S. 819 (1986).

For the same underlying reason, the antitrust laws protect only *lawful* competition—not competition in markets for illegal goods or services, such as infringing products. See *Bement* v. *National Harrow Co.*, 186 U.S. 70, 92 (1902); see also, *e.g.*, *In re Canadian Import Antitrust Litig.*, 470 F.3d 785, 789-792 (8th Cir. 2006) (non-FDA-approved prescription medications); *Access Telecom, Inc.* v. *MCI Telecomms. Corp.*, 197 F.3d 694, 712-713 (5th Cir. 1999) (export from the United States of telecommunications services illegal in the country of import), cert. denied, 531 U.S. 917

(2000). Indeed, the federal government's own compliance guidelines recognize that licensors and licensees are potential competitors only if they would compete in the absence of a license. The government finds licensing agreements anticompetitive when the "arrangement harms competition among entities that *would have been actual or likely potential competitors* in a relevant market in the absence of the license." DOJ & FTC, Antitrust Guidelines for the Licensing of Intellectual Property § 3.1 (1995) (emphasis added), www.justice.gov/atr/public/guidelines/0558.htm (last visited Feb. 27, 2013).

Of course, whether a patent license *is* necessary for lawful competition is the very issue being settled by the parties in Hatch-Waxman litigation. But under elemental principles of antitrust and patent law, there is no basis for assuming—as the FTC's rule of presumptively illegality does—that a license is unnecessary. To the contrary, patents must be presumed valid. See 35 U.S.C. 282; *Roper Corp.* v. *Litton Sys., Inc.*, 757 F 2d 1266, 1270 (Fed. Cir. 1985) ("A patent is born valid," and so remains "until a challenger proves" otherwise.). Indeed, this Court recently reaffirmed that Congress intended the presumption of validity to be overcome only by "clear and convincing evidence." *Microsoft Corp.* v. *i4i Limited Partnership*, 131 S. Ct. 2238 (2011). A pharmaceutical patent, which confers "a monopoly over the manufacture and distribution of the patented invention," is therefore presumed valid, and "[a] settlement is not unlawful if it serves to protect that to which the patent holder is legally entitled." *Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d at 1337.

Moreover, a party—such as the FTC here—seeking to invalidate a restraint bears the burden of establishing the predicate for its condemnation, including the existence of a restraint of trade. See *Continental T.V., Inc.* v. *GTE Sylvania, Inc.*, 433 U.S. 36, 49 (1977); *FTC* v. *Indiana Fed'n of Dentists*, 476 U.S, 447, 461 (1986) ("finding[s]" supported conclusion "that the challenged restraint was unreasonable"). Here, there is no "restraint" on competition at all unless the FTC can demonstrate that the alleged infringer is indeed a potential (*i.e.*, lawful) competitor. See *Sargent Elec.*, 785 F.2d at 1127. Yet the FTC's contrary rule of presumptive illegality turns this elemental principle on its head by, in effect, resolving against the patentee the question whether the would-be generic could lawfully enter the market absent a license.

The "scope of the patent" test, in short, takes account of the fact that no restraint of competition exists unless the parties are *shown* to be lawful potential competitors. The FTC's reliance on the principle that " '[t]he anti-trust laws are as much violated by the prevention of competition as by its destruction,' " Pet. Br. 20-21 (quoting *United States* v. *Griffith*, 334 U.S. 100, 107 (1948)), is accordingly misplaced. The FTC cites cases, where, for example, two asserted competitors "agreed not to compete in the other's territories." *Palmer* v. *BRG of Ga., Inc.*, 498 U.S. 46, 49 (1990) (per curiam); see Pet. Br. 20. But that principle has no application here. The question whether the parties *are* lawful potential competitors is the very issue the parties agreed to settle in the Hatch-Waxman litigation. And the FTC itself recognizes that the antitrust litigation should not require the court to determine how the patent suit would have been resolved. Pet. Br. 53-55. That is why this Court has recognized that "[w]here

there are legitimately conflicting [patent] claims or threatened interferences, a settlement by agreement, rather than litigation, is not precluded by the [antitrust laws]." *Standard Oil Co.* v. *United States*, 283 U.S. 163, 171 (1931).

(ii) The scope of the patent test also secures for consumers the long-term benefits of preserving investments in life-saving and life-improving innovation and, in some cases, accelerating generic entry, thereby reducing costs for consumers. See Part I, *supra*. This Court recognizes that antitrust rules must take into account the long-run benefits (or detriments) to consumers. See *Verizon Commc'ns, Inc.* v. *Law Offices of Curtis* v. *Trinko*, 540 U.S. 398, 412–415 (2004) (rejecting proposed new Section 2 rule that was not in consumers' long-run best interests under a cost and risk-of-error analysis); see also, *e.g.*, *Brooke Grp.*, 509 U.S. at 226-227 (emphasizing that the high standard for predatory pricing safeguards against the possibility of "standards * * * so low that antitrust suits themselves bec[o]me a tool for keeping prices high").

The FTC's proposed test fails to consider the full range of procompetitive effects. Hatch-Waxman settlements bring both short- and long-term procompetitive benefits. In the short term, such settlements frequently carry the immediate procompetitive benefit of permitting generic entry, prior to the expiration of the patent. See Part I.B, *supra*. In the long run, they foster procompetitive innovation. See Part I.A, *supra*. The FTC would have this Court ignore such settlements' short- and long-run benefits to consumer welfare and instead maximize certain purported short-term consumer benefits by forcing the parties to settle on different terms (or not settle at all). But that rule

would preclude the benefits of many procompetitive settlements, such as where the innovator would have prevailed, and the generic's entry would have been further delayed, had the suit been litigated to judgment. Moreover, in the long run, the FTC's rule would hinder innovation and consumer welfare.

More fundamentally, the antitrust laws impose no duty upon the parties to maximize competition. "The Sherman Act * * * does not give judges carte blanche to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition." *Trinko, LLP*, 540 U.S. at 415-416 (internal quotation marks and citation omitted). "There is simply no precedent for [the] argument that the parties to a settlement are required to preserve the public's interest in lower prices." *In re Ciprofloxacin Antitrust Litig.*, 363 F. Supp. 2d 514, 540-541 (E.D.N.Y. 2005), aff'd, 544 F.3d 1323 (Fed. Cir. 2008), cert. denied, 557 U.S. 920 (2009). Heeding this basic principle is all the more important where, as here, improperly forcing parties to maximize competition in the short-run will ultimately harm consumers in the long run. See *Trinko*, 540 U.S. at 412-415; *Brooke Grp.*, 509 U.S. at 226-227

(iii) Not only does the "scope of the patent" test accord with elemental antitrust and patent principles, but it is also administrable and reduces enforcement costs and the risk of enforcement error. As this Court has recognized, the risk of error is especially important in devising appropriate antitrust doctrines, because "[m]istaken inferences and the resulting false condemnations * * * chill the very conduct the antitrust laws are designed to protect." *Trinko*, 540 U.S. at 414 (quoting *Matsushita Elec. Indus. Co.* v. *Zenith Radio*

Corp., 475 U.S. 574, 594 (1986)); see, *e.g.*, *id.* (finding that "[t]he cost of false positives counsel[ed] against an undue expansion of § 2 liability"). In *Credit Suisse Sec. (USA) LLC* v. *Billing*, for example, this Court rejected application of the antitrust laws in the context of alleged violations of the securities laws, largely because "antitrust courts [we]re likely to make unusually serious mistakes" and chill desirable conduct. 551 U.S. 264, 282-283 (2007).

Here, consideration of enforcement costs and the likelihood of error counsel strongly in favor of the "scope of the patent" test. In the absence of special circumstances suggesting that the underlying litigation was a sham or fraudulent, see pp. 21-22, *supra*, administering the test requires only that a court determine whether the restraint imposed by a settlement extends beyond the scope of a patent. See, *e.g.*, *Ciprofloxacin*, 544 F.3d at 1333 (upholding settlement because its terms were "well within [plaintiff's] rights as the patentee"). If, on the other hand, a settlement restricts competition outside the patent's scope, or is the result of sham or fraudulent litigation, it may be subject to further challenge.

3. The FTC's proposed "quick look" approach lacks foundation

Finally, there is no basis for the FTC's proposal to subject settlements with consideration flowing to an alleged infringer to a presumption of illegality under a "quick look" approach. Any departure from the rule of reason requires a significant justification. See, *e.g.*, *Bus. Elecs. Corp.* v. *Sharp Elecs. Corp.*, 485 U.S. 717, 724 (1988). Thus, this Court has rejected the quick-look mode of analysis where conduct "might plausibly be thought to have a net procompetitive effect." *Cal.*

Dental, 526 U.S. at 771. A quick look is appropriate only where "the great likelihood of anticompetitive effects can be easily ascertained," and the court can make "a confident conclusion about the principal tendency of a restriction." *Id.* at 770, 781. Here, no such "conclusion" can be reached with "confiden[ce]."

For one thing, contrary to the FTC's notably qualified assertions that Hatch-Waxman settlements with consideration flowing to alleged infringers have "manifest anticompetitive *potential*" and are "*generally* devoid of any countervailing virtue," Pet. Br. 17, 34 (emphasis added), such settlements, as demonstrated, secure numerous procompetitive benefits. See Part I, *supra*.

For another, the FTC's proposed rule erroneously assumes that such settlements extinguish competition the Sherman Act protects, whereas that is the very issue being settled. See pp. 23-26, *supra*. The FTC's entire argument hinges on the possibility that, with respect to *some* settlements, if the parties had not settled the litigation, the patentee would ultimately have lost. See, *e.g.*, Pet. Br. 16 (referring to the settling patentee's "*artificially prolonged* period of market exclusivity") (emphasis added). As explained, elemental antitrust and patent principles preclude presuming the patentee would have lost, and preclude disregarding the long-term adverse consequences for consumers of undermining patent rights in order to maximize certain short-term benefits.

The FTC's retort—that the fact of consideration to the alleged infringer shows that the patentee likely would have lost, Pet. Br. 44-45—lacks foundation. As demonstrated above, such settlements are driven not by the likelihood that the innovator's patent is invalid,

but by the massive investment that is at stake for the innovator, the risk of litigation error, and the parties' asymmetric risks under the Hatch-Waxman framework. Indeed, as discussed above, see pp. 15-16, *supra*, in numerous cases, innovators have entered into settlements with infringers that might have run afoul of the FTC's proposed rule, yet the innovators' patents were upheld in subsequent litigation. See, *e.g.*, *Sanofi-Aventis* v. *Apotex, Inc.*, 659 F.3d 1171, 1175-1176 (Fed. Cir. 2011). In such cases, without the settlements the FTC condemns, the innovator would have been able to exclude the generic during the *entire* patent term. In fact, data reflecting the outcomes of Hatch-Waxman litigation to decision over the last decade suggests that patentees prevail more often than not. See p. 15, *supra*. The mere possibility that competition will be restrained in some unknown proportion of cases in which, in the absence of such a settlement, the generic challenger might have won, cannot support "a confident conclusion" that such settlements have a "principal tendency" to restrict competition. *Cal. Dental*, 526 U.S. at 781.

There is, in short, no basis for concluding that settlements with consideration flowing to alleged infringers have "manifestly anticompetitive effects," let alone that they "lack * * * any redeeming virtue." *Leegin Creative Leather Prods.*, 551 U.S. at 886. There is thus no justification for "quick look" condemnation.

B. The FTC's Unworkable Rule Would Disserve Innovation And Consumers

The FTC's proposed "quick look" approach not only lacks foundation, but is also fundamentally unworkable. It would severely diminish if not destroy innovators' ability to obtain repose from the onslaught

of patent litigation that inevitably plagues their successful new products—and would ultimately thereby harm consumers.

The FTC's own account of how a party might rebut its rule of presumptive illegality shows that the rule is unworkable. See Pet. Br. 37-38. The FTC concedes that there is "no fixed formula" for rebuttal and suggests that the "court would need to consider the totality of the circumstances surrounding the agreement," including a lengthy list of highly fact-intensive factors touching on, *inter alia*, "industry standards," "previous dealings between the parties," a "demonstrated interest in or need for the property or services on the part of the brand-name manufacturer," and the entire "course and content of the * * * negotiations." *Ibid.* Under such an amorphous test, no party to a settlement involving consideration flowing to the would-be generic could feel confident of victory in defending the settlement, no matter whether the consideration was indeed "bona fide." *Id.* at 37.

Worse, in many cases, the FTC's rule would require the parties to litigate the merits of the very patent dispute the parties sought to settle. The FTC purportedly concedes that "[a]dministrative concerns * * * strongly disfavor" forcing the settling parties to litigate the merits of the underlying dispute, and, indeed, concedes that such a requirement would be a "powerful disincentive to settlement." Pet. Br. 54. Yet the FTC's test would require just such a relitigation whenever an innovator attempted to defend its presumptively unlawful settlement on the ground that its patent was, in fact, valid and infringed, so that any delay prior to generic entry imposed no anticompetitive effect. Moreover, as even the FTC concedes in

a euphemistic fashion, "[q]uantification of damages in a private antitrust action might require an assessment of *what sequence of events would likely have ensued* in the absence of a reverse payment." *Id.* at 55 n.11 (emphasis added).

Such an undertaking would be extremely onerous, increasing enforcement costs and taxing judicial economy—including in this very case. See Pet. App. 33a ("In this case, assaying the infringement claim 'as of the time of settlement' would have required mining through mountains of evidence—when the lawsuit settled, more than 40 depositions had been taken and one side alone had produced more than 350,000 documents."). As the court of appeals below recognized, "[t]he settlement made that [undertaking] unnecessary, but the FTC's approach would put that burden back on the parties and the court, undo much of the benefit of settling patent litigation, and discourage settlements." *Ibid.* And the burden is not just one of marshaling potentially large amounts of evidence, but also of proving the almost-unprovable: "It is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case," *Whitmore* v. *Arkansas*, 495 U.S. 149, 159-160 (1990), and "retroactively predicting from a past perspective a future that never occurred is even more perilous," Pet. App. 32a.

Furthermore, under such a regime, forced to litigate the hypothetical outcome of a hypothetical patent trial, an innovator faces the same if not greater risk of litigation error that led it to settle the Hatch-Waxman litigation in the first place. As the court below noted, this post-hoc, retrospective inquiry would be "unlikely to be reliable," in part because the determinations

would be left to the "non-specialized circuit courts [that] have no expertise or experience in the area" and are admittedly "ill-equipped to make a judgment about the merits of a patent infringement claim." Pet. App. at 33a-35a. By contrast, the "scope of the patent" test avoids the burdens and risks of "a patent case within an antitrust case about the settlement of the patent case." *Id.* at 36a.

The uncertain—and potentially extremely wide-ranging—breadth of the FTC's proposed rule would further chill procompetitive settlements. The FTC's suggestion, Pet. Br. 40, that other forms of consideration may be acceptable under its rule rings hollow. The FTC has taken the position that nearly any form of settlement can be characterized as a verboten "payment" constituting "*prima facie* evidence of an unreasonable restraint of trade" under the Third Circuit's decision in *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (2012). See FTC Brief as Amicus Curiae, *In re Effexor XR Antitrust Litig.*, No. 3:11-cv-05479, 1-2 (D.N.J. Aug. 10, 2012) (quoting *K-Dur*, 686 F.3d at 218). In the *Effexor* case, for example, the FTC contends that an innovator's exclusive licensing of an alleged generic infringer for the generic version of Effexor XR during the alleged infringer's 180-day exclusivity period—which means that the innovator itself would not issue its own "authorized generic" version during that period—alone constitutes an anti-competitive "payment." The FTC has thus asserted that it regards *any* consideration to the alleged infringer as a potentially illicit "reverse payment."

Confronted with the likely prospect of a post-settlement enforcement action by the FTC or private treble damages suits, parties may instead choose to lit-

igate their Hatch-Waxman suits to final judgment, depriving the public of all the potential benefits of settlement identified above, see Part I, *supra*. Innovators will incur burdensome costs and face the prospect of unknown and potentially incorrect litigation outcomes that may decrease incentives to innovate. See *Ciprofloxacin*, 261 F. Supp. 2d at 256; Crane, 88 Minn. L. Rev. at 706 ("[R]estricting patent settlements will have the effect of increasing the anticipated costs of litigation for any firm considering entering a patent-intensive market."). "[T]he results will be fewer new drugs that have led in the past to healthier and more productive lives for U.S. customers and large gains to the U.S. economy." *Ciprofloxacin*, 261 F. Supp. 2d at 256; see also *Valley Drug*, 344 F.3d at 1309 (similar).

* * *

The FTC's proposed rule would hinder innovation and disserve the interests of consumers. This Court should instead apply traditional principles of antitrust and patent law to conclude, as have the majority of courts of appeals, that parties to bona fide patent disputes may settle such litigation on the terms of their choosing, as long as those terms do not exceed the scope of the patent.

CONCLUSION

The judgment of the Court of Appeals should be affirmed.

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AMICUS CURIAE BRIEF

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Petitioner,

v.

WATSON PHARMACEUTICALS, INC., *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF OF THE PUBLIC PATENT FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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INTEREST OF THE *AMICUS CURIAE*[1]

The Public Patent Foundation ("PUBPAT") is a not-for-profit legal services organization affiliated with the Benjamin N. Cardozo School of Law. PUBPAT achieves its mission of protecting freedom in patent system by representing the public interest against undeserved patents and unsound patent policy. PUBPAT has argued for sound patent policy before this Court, various Courts of Appeals and District Courts, Congress, the U.S. Patent & Trademark Office (PTO), and many other national and international bodies. PUBPAT has also successfully challenged specific undeserved patents causing significant harm to the public through both litigation and administrative proceedings. *See, e.g.*, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (2012). PUBPAT is a leading provider of public service patent legal services and advocate for comprehensive patent reform.

PUBPAT has an interest in this matter because the decision of this Court will have a significant effect on the public interest represented by PUBPAT. More specifically, PUBPAT represents the public interest in ensuring that only valid patents remain in force so that full and fair competition can take place without the impediment of improperly granted patents. Unfortunately, our patent system today is severely flawed in ways that cause mass

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[1] In accordance with Supreme Court Rule 37.6, *Amicus Curiae* states that: (1) no counsel to a party authored this brief, in whole or in part; and (2) no person or entity, other than amicus, their members and counsel have made a monetary contribution to the preparation or submission of this brief. Copies of consents from the parties to file this brief have been provided to the Clerk.

production of low-quality patents. Anticompetitive reverse-payment agreements between patent-holding brand name pharmaceutical companies and potential generic challengers eliminate Congressionally intended and socially beneficial incentives for those potential generic challengers to compel judicial review of invalid patents. Allowing the holders of bogus patents to bribe would-be challengers to those patents to drop their challenge causes substantial public harm.

PUBPAT believes this brief, authored by a registered patent attorney and professor of patent law, provides the Court with relevant legal and factual information that may not otherwise be brought to its attention. This is especially true because PUBPAT has particular experience with issues relating to patent quality and the critical role the judicial process plays in the Constitutionally intended checking of illegitimate governmental encroachment on freedom and free markets through an ever-increasing issuance of unjustified patents.

SUMMARY OF ARGUMENT

People unfamiliar with the patent system, including specifically the Court of Appeals in this case, tend to give patents entirely too much credit. Rather than being rock-solid undeniable fortresses of legal dominance over the claimed subject matter, patents today are nothing more than some overly worked patent examiner's decision to allow claims requested by an applicant. They result from a Patent Office with perverse incentives to grant, rather than deny, applications and, in reality, give their owner nothing more than, at best, a fifty-fifty chance of

having any exclusionary power at all. In fact, in the vast majority of pharmaceutical patent cases, 70% or more, the generic challenger wins.

As such, the Court of Appeals' assumption that a given patent has a potential exclusionary power equal to its full term is factually meritless and legally unsustainable. The Court of Appeals also erred by failing to recognize the substantial pro-competitive benefits of legal challenges to patents, and in particular the judiciary's critical role in checking patent quality and patent scope, which this Court has repeatedly recognized. In short, earnest patent litigation is pro-competitive, as are legitimate settlements thereof that recognize the relative strengths and weaknesses of the parties' respective positions. However, settlements with transparent bribes for challengers to take a dive cannot be reconciled with any sound public policy or legal precedent.

ARGUMENT

I. COURT CHALLENGES TO PATENTS ARE A NEEDED CHECK ON THE PTO'S RUBBER STAMPING OF INVALID CLAIMS TO PUBLIC PROPERTY

Quality is the single most important issue in our patent system, because without quality, the system risks losing credibility and the support of the American people. We must, above all other goals, ensure that only deserving patents are issued and maintained, otherwise the public will become rightfully skeptical of the merits of any patent and the patent system as a whole. Permitting anticompetitive reverse payments that incentivize

legitimate challengers to undeserved patents to drop their challenges harms the public by shielding undeserved patents from critical judicial review. The Court of Appeals' decision to offer safe harbor for such clear bribes to drop challenges to patents so that their owners can continue to charge monopolistic prices for the covered product betrays common sense, sound public policy, and, most importantly, the clear law of this Court.

A. Patent Quality In The United States Today Is Extremely Poor

The current level of quality for U.S. patents is extremely poor. There are several independent sources, including the Patent Office's own data, that prove this to be true.

For one, an ongoing project of the University of Houston Law School, known for having one of the most reputable patent departments in the country, tracks the results of patent litigation and empirically categorizes those results according to the specific issues involved with each case. *See* Patstats, available at http://www.patstats.org/. Its data shows that approximately 30% of all issued patents reviewed by courts in recent years were found to lack novelty, meaning they claimed subject matter that was identical to what was already in the prior art. Further, another 40% of the remaining patents reviewed by courts were found invalid for being obvious in light of the prior art. 35 U.S.C. § 103; *See* Univ. of Houston Law Ctr. Inst. for Intellectual Prop. & Info. Law, Full Calendar Year 2010 Report, http://www.patstats.org/2010_full_year.rev5.htm; Univ. of Houston Law Ctr. Inst. for Intellectual Prop.

& Info. Law, Full Calendar Year 2011 Report, http://www.patstats.org/2011_Full_Year_Report.html.

Although the cited Patstats data is limited to only the very small portion of issued patents that are litigated to a judgment, litigated patents tend to have a much greater significance to the public, on average, than non-litigated patents. John R. Allison, Mark A. Lemley, Kimberly A. Moore & R. Derek Trunkey, *Valuable Patents*, 92 Georgetown Law Journal 435 (2004). The technology related to litigated patents is by definition valuable to a certain extent, as it at least merits the related cost of patent litigation, which prevents the litigation of worthless patents. Thus, any mistakes regarding the validity of litigated patents causes meaningful public harm by denying the public access to the covered technology during the period between the patent's wrongful issuance by the Patent Office and its invalidation by the courts.

The PTO's own statistics show that more than 90% of all the patents that it granted that it is later asked to review (through a procedure called reexamination) have at least one "substantial question of patentability." *Inter Partes Reexamination Filing Data June 30, 2012*, USPTO, http://www.uspto.gov/patents/stats//IP_quarterly_report_June_30_2012.pdf ("*Inter Partes* Report") (94% of all requests for *inter partes* reexamination granted); *Ex Parte Reexamination Filing Data - June 30, 2012*, USPTO, http://www.uspto.gov/patents/stats/EP_quarterly_report_June_30_2012.pdf ("*Ex Parte* Report") (92% of all requests for *ex parte* reexamination granted); 35 U.S.C. § 312. Looking

deeper, the PTO's data shows that 89% of patents challenged through the *inter partes* reexamination process, which allows for ongoing participation by the challenger, are canceled or changed, while more than 78% of patents challenged through the *ex parte* reexamination process, which does not allow the challenger to participate after submitting the initial request, have their claims canceled or changed. *Inter Partes Report* (all claims canceled 42% of the time, claims changed 47% of the time); *Ex Parte Report* (all claims canceled 11% of the time, claims changed 67% of the time).

One way to confirm how grim the state of affairs is for U.S. patent quality is to compare our system's patent application outcomes to those of other well-respected patent offices. Firstly, the PTO ultimately grants patents from 78% of all original applications, while that rate is only 61% in Japan and 55% in the European Union. Cecil D. Quillen, Ogden D. Webster, and Richard Eichman, *Continuing Patent Applications and Performance at the U. S. Patent and Trademark Office-One More Time*, 18 Fed. Cir. B.J. 379 (2009) (http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1429809).

An even better comparative picture is drawn by a study of roughly 70,000 issued U.S. patents and their corresponding foreign applications, which found that counterparts to patent applications *issued in the U.S.* were issued by (i) the European Patent Office only 72.5% of the time, (ii) the Japanese Patent Office only 44.5% of the time, and (iii) both the EPO and JPO only 37.7% of the time. Paul H. Jensen, Alfons Palangkaraya & Elizabeth Webster, *Disharmony in International Patent Office Decisions*,

16 Fed. Cir. B.J. 679 (2006). This evidence shows that the U.S. Patent Office is indeed granting a very disproportionally high number of patents relative to the rest of the world.

In short, it is not unfair to accuse the U.S. Patent and Trademark Office of being a rubber stamp, approving virtually any private claim made to it, regardless of whether the claimed subject matter is in the public domain or not. The overarching cause of poor patent quality is not, however, incompetence at the PTO, but rather perverse incentives on it and other actors within the patent system that reward the issuance of patents without regard any concern for quality.

For example, the Patent Office receives roughly ten times as much money from issuing a patent than it does from denying a patent. This is because the Patent Office charges an "Issuance Fee" to issue a patent after the application has been approved and then also "Maintenance Fees" every four years of a patent's life in order to keep it enforceable. *See, e.g.*, United States Patent and Trademark Office Fee Schedule, http://www.uspto.gov/about/offices/cfo/finance/fees.jsp (effective September 26, 2011) (charging $380 for basic filing fee, $620 for search fee, and $250 for examination fee, each of which is required to apply for a patent, but then $1,740 for issue fee and $1,130 for 3.5-years maintenance fee, $2,850 for 7.5-years maintenance fee, and $4,730 for 11.5-years maintenance fee). Thus, the USPTO is financially incentivized to grant rather than deny patents, as it is a fee-funded agency. Michael Frakes and Melissa F. Wasserman, *Does Agency Funding Affect Decisionmaking?: An*

Empirical Assessment of the PTO's Granting Patterns, 66 Vand. L.R. 2013 (2012) (http://ssrn.com/abstract=1986542).

An arms race amongst patent holders encourages the acquisition of as many patents as possible, regardless of validity, to be used as threats against or bargaining chips with others. Even examiners themselves are encouraged to issue bad patents under the "count" quota system that measures their performance, because issuing a patent takes no more work than a simple signature, while denying a patent requires countless hours of letter and brief writing to continue making and supporting a rejection. *Recently Announced Changes to USPTO's Examiner Count System Go Into Effect*, USPTO (2010) (http://www.uspto.gov/news/pr/2010/10_08.jsp) ("The revised count system that is now in effect is designed to: ... Encourage examiners to identify allowable subject matter earlier in the examination process."). In short, very few actors have any incentive to purge the patent system of the hundreds, if not thousands, of invalid patents issued by the Patent Office every week.[2]

B. Undeserved Pharmaceutical Patents Cause Substantial Public Harm

Brand name pharmaceutical companies implement a purposeful plan to seek and obtain as much patent protection for their drugs as possible. When developing a new drug, they first go to the Patent Office to secure patents on the broad genus of chemical entities they are pursuing, not yet

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[2] The Patent Office issues approximately 4,500 patents every Tuesday, which is the day of the week patents are granted.

knowing which species within that genus will lead to an actual marketable drug. *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012).

Later, when they isolate particular species of the genus that seem promising, they apply for patents on those species, arguing that the species' particular characteristics were not obvious in light of the previous disclosure of the genus, although it was of course the pharmaceutical company's intention all along to identify the most promising species from within the genus, and methods for doing so are well known within the pharmaceutical arts.

After identifying promising species compounds, the next series of patents sought by the pharmaceutical company are drawn to particular formulations of those species, including salts, prodrugs, enantiomers, crystallized forms, and other common chemical derivatives. Amy Kapczynski *et al.*, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, PLOS ONE, e49470, at 6 (Dec. 2012). The formulations are not safer or more efficacious than the species themselves. They are merely more stable compositions for production and distribution purposes.

While methods for developing stable formulations of chemical entities have been well known for decades, the pharmaceutical company will nonetheless argue to the Patent Office, should it even makes any objections to the claims, that it was not obvious that those same tried-and-true formulation techniques would work on their new chemical species. While such a lame argument is

sufficient to satisfy the Patent Office's rubber-stamp standards, the courts have routinely struck such patents as obvious. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007) ("[W]e hold that the optimization of the acid addition salt formulation for an active pharmaceutical ingredient would have been obvious where as here the acid addition salt formulation has no effect on the therapeutic effectiveness of the active ingredient and the prior art heavily suggests the particular anion used to form the salt.").

Later still come the "method of use" patents that allow pharmaceutical companies to pretend they did not intend or expect to use their previously patented drug in the particular way over which they now wish to claim exclusivity. *Caraco Pharm*, 132 S. Ct. at 1676. It's a three-card-Monte shell came of the Canal street variety. If you think you know where the Queen is, and you have your finger on it, the pharmaceutical company will lift up a different card and show you they have one there, too. In truth, pharmaceutical companies are not to be maligned for doing what is in their self interest: getting as many patents as possible for their drug, because any patent can have substantial value in delaying competition.

In this case, Solvay and Besins have filed no less than twenty-one additional applications for patents on the same drug. A simple review of the PTO's Patent Application Information Retrieval (PAIR) database (available at http://portal.uspto.gov /external/portal/pair) shows that each of the following applications claim priority to the '894 patent disclosure:

- 09/703,753 filed on 11-01-2000
- 10/033,101 filed on 10-19-2001
- 10/046,454 filed on 10-19-2001
- 10/098,232 filed on 03-15-2002
- 10/153,468 filed on 05-21-2002
- 10/248,267 filed on 01-03-2003
- 10/273,484 filed on 10-18-2002
- 10/787,071 filed on 02-25-2004
- 10/825,540 filed on 04-15-2004
- 10/828,678 filed on 04-20-2004
- 10/829,618 filed on 04-20-2004
- 10/867,435 filed on 06-14-2004
- 10/867,445 filed on 06-14-2004
- 10/925,421 filed on 08-24-2004
- 13/071,264 filed on 03-24-2011
- 13/071,276 filed on 03-24-2011
- 13/275,232 filed on 10-17-2011
- 13/275,254 filed on 10-17-2011
- 13/343,170 filed on 01-04-2012
- 13/430,862 filed on 03-27-2012
- 13/648,694 filed on 10-10-2012

Notice that the most recent application was just filed in October, nearly ten years after the '894 patent was issued. While many of these applications have been abandoned, five are still pending and could indeed mature into patents. More applications could also be filed. While some may find this carpet-bombing of patent applications to be outrageous, it is commonplace, as applicants know that the rubber-stamp PTO will likely grant at least some patents from the deluge of applications. If patent application bombardment did not result in issued patents, actors like Solvay and Besins would not try it. Whether any of those issued patents would

actually stand up in court is unimportant. All they need for delay is an issued patent, not a legitimate one.

As may be transparent to even the most casual interested observer, the later generations of pharmaceutical patents have increasingly weaker validity, in large part because all the previous patents become prior art to the later patents. Thus, a patent on a new chemical entity is often valid, while a later patent on a particular formulation or a particular method of use is more likely to be invalid. What's important about this process, referenced as "secondary" or "evergreening" patenting in the literature, is that all of these patents can be, and typically are, listed in the Orange Book for a particular drug. Thus, frequently generic ANDA filers do not challenge the earliest of patents, but instead the second, third, fourth, and later generation derivative patent, whose arguably novel aspect likely has nothing to do with the underlying active pharmaceutical ingredient at all. C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. Empirical Legal Stud. 613, 621 (2011). As a perfect example, in this case it is not the underlying pharmaceutical ingredient that is claimed by the challenged patent, but instead a formulation of that public-domain pharmaceutical agent with a certain recipe of excipients, i.e. well known inactive ingredients, like sugar, that perform the function of carriers for the active ingredient in order to make a producible, deliverable, and storable drug product.

Generally speaking, undeserved patents cause substantial harm to the American public, because an issued patent – regardless of its true legitimacy – can be used to threaten and impede otherwise permissible, socially desirable, conduct. The threat of having to incur the costs and potential liability of a patent lawsuit is one that few individuals or small businesses can withstand,even if the patent is of doubtful validity. This chilling effect, when caused by a patent that would be ruled invalid if challenged, provides no social benefit to the American people, because the patent contains nothing new; its invalidity means that whatever it claims or describes was either already known or was obvious in light of what was already known. Particularly in the area of needed medicines, poor patent quality can be devastating to the American people by improperly taxing legitimate businesses, deterring competition and raising consumer prices.

Undeserved pharmaceutical patents can be listed in the Orange Book and then asserted in ANDA litigation to block generic competition to what should in reality be a public domain drug. For example, there have been several patents that were used to preclude competition in pharmaceutical markets worth billions of dollars that were later proven to be undeserved. *See, e.g., Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007) (patent preventing competition to $1.2 billion per year hypertension and coronary artery disease drug, Norvasc, proven invalid); *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368 (Fed. Cir. 2001) (patent preventing competition to $1.6 billion per year cancer treatment, Taxol, proven invalid); *Eli Lilly & Co. v. Barr Labs.*, 251 F.3d 955 (Fed.

Cir. 2001) (patent barring alternatives to $2.9 billion per year antidepressant medication, Prozac, proven invalid).

Indeed, studies of pharmaceutical patents subjected to litigation highlight the need for such scrutiny, as they show that generics prevail in proving asserted pharmaceutical patents either invalid or not infringed seventy to seventy-three percent of the time. Janicke & Ren, *Who Wins Patent Infringement Cases?*, 34 AIPLA Q.J. 1, at 21 (2006) (Chart 1, labeled "Percentage of Dispositive Cases Won by Plaintiffs in Various Technologies" indicates 30% for "Chemical (pharm.)" cases). Further, as the Third Circuit just this past summer noted:

> Many patents issued by the PTO are later found to be invalid or not infringed, and a 2002 study conducted by the FTC concluded that, in Hatch-Waxman challenges made under paragraph IV, the generic challenger prevailed seventy-three percent of the time. See FTC, *Generic Drug Entry Prior to Patent Expiration* 16 (2002), available at http://www.ftc.gov/os/2002/07/genericdrug study.pdf; Kimberly A. Moore, *Judges, Juries, and Patent Cases — An Empirical Peek Inside the Black Box*, 99 Mich. L.Rev. 365, 385 (2000) (noting that between 1983 and 1999 the alleged infringer prevailed in forty-two percent of patent cases that reached trial).

In re K-Dur Antitrust Litigation, 686 F.3d 197, at 215 (3rd Cir. 2012).

> The Pharmaceutical Research and Manufacturers of America points to a more recent study concluding that, in the years from 2000 to 2009, generics prevailed in slightly less than half of their challenges. RBC Capital Mkts., Pharmaceuticals: Analyzing Litigation Success Rates 4 (2010), available at http://www.amlawdaily.typepad.com/pharmareport.pdf. Even if the industry's own figures are accepted, they show that a substantial fraction of Hatch-Waxman patent challenges succeed on the merits. Moreover, the study cited by the industry further states that "when you take into account patent settlements and cases that were dropped, the success rate for generics jumps to 76%, substantially in favor of challenging patents."

Id. at fn 11.

C. Court Challenges Can Alleviate The Public Harm Caused By Invalid Pharmaceutical Patents

Given the low standard for obtaining patents in our country, it is no wonder that pharmaceutical patent owners seek to avoid challenges made to the legitimacy of their claimed rights. It's rational for them to list such patents in the Orange Book as this delays the introduction of generic competition through the automatic 30 month stay in FDA approval of the generic. It is also entirely rational to then pay off any generic competitor that challenges the patent to preserve the patent's apparent legitimacy for use when another generic drug company files an ANDA. Courts can, and should, quash this opportunistic behavior by disallowing

anticompetitive reverse-payment settlements that do an end-run around full and fair adjudication of the validity challenge mounted to the patent by the first generic challenger. Such challenges would help purge meritless patents from society, which is an entirely pro-competitive result.

This Court has recognized that discouraging anticompetitive settlements of patent infringement cases has, in itself, a pro-competitive effect. Accused infringers who prove a patent invalid perform an important public service by correcting the PTO's errors on their own nickel. See *Lear v. Adkins*, 395 U.S. 653, 670 (1969) (explaining that if those "with economic incentive to challenge the patentability of an inventor's discovery" do not do so, "the public may continually be required to pay tribute to would be monopolists without need or justification"); *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892) ("[i]t is as important to the public that competition should not be repressed by worthless patents as that the patentee of a really valuable invention should be protected in his monopoly"). Even those who try but fail to prove a patent invalid perform a public service by narrowing uncertainty as to the patent's validity, thus encouraging others to respect it. *Kloster Speedsteel AB v. Crucible, Inc.*, 793 F.2d 1565, 1581 (Fed. Cir. 1986).

Similarly, accused infringers who do not raise invalidity challenges to an asserted patent, but instead raise substantial noninfringement defenses also aid competition because their efforts lead to a judicial opinion declaring the patent's metes and bounds, on which the public may rely. Determining the true scope of a patent is accomplished by the

courts through a process called claim construction, which is often difficult, as evidenced by the fact that the U.S. Court of Appeals for the Federal Circuit reverses over 38% of district court claim constructions. *See* David L. Schwartz, *Practice Makes Perfect? An Empirical Study of Claim Construction Reversal Rates in Patent Cases*, 107 Mich. L. Rev. 223 (2008). As such, a party that litigates the scope of a patent through the stage of claim construction aids the public in determining what the patent covers and, more importantly, what it does not. These significant pro-competitive effects that result from the discouragement of anti-competitive settlements went unrecognized by the Court of Appeals in this case.

Further, the Court of Appeals failed to recognize that application of sound antitrust law and policy comports with the policies implemented in the Hatch-Waxman Act. The entire point of Hatch-Waxman was to encourage and protect competition in the pharmaceutical industry, which it did in two principal ways: (i) making it easier for competition to already available products to be introduced; and (ii) encouraging new innovative products to be brought to market by strengthening patent rights. *See* H. Rep. No. 98-857(I). Unfortunately, pharmaceutical companies, both brand and generic, have circumvented the pro-competitive intent of Hatch-Waxman by sharing monopoly profits made by one of them instead of competing with one another in the marketplace. Lara J. Glasgow, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?*, 41 IDEA 227 (2001) (explaining that the Act is "littered with loopholes"). By condoning net-anticompetitive

gaming of the Hatch-Waxman regime through patent infringement litigation settlement agreements, the Court of Appeals' decision will frustrate, not promote, Hatch-Waxman's goals.

CONCLUSION

For the foregoing reasons, this Court should reverse the Court of Appeals decision below and hold that reverse-payment agreements are presumptively anticompetitive and unlawful.

Respectfully submitted,

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AMICUS CURIAE BRIEF

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Petitioner,

v.

ACTAVIS, INC., ET AL.,

Respondents.

On Writ of Certiorari
to the United States Court of Appeals
for the Eleventh Circuit

BRIEF FOR SHIRE PLC AS *AMICUS CURIAE* SUPPORTING RESPONDENTS

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INTEREST OF AMICUS CURIAE

Shire plc ("Shire") is a mid-size pharmaceutical company that markets products in the United States and over 50 countries worldwide.[1] Shire's portfolio of innovative products includes treatments for rare conditions such as hereditary angioedema (a blood disorder that causes acute, episodic swelling of the airway, gastrointestinal tract, face, and extremities) and Hunter's Syndrome (a genetic condition that causes permanent and progressive damage affecting appearance, mental development, organ function, and physical abilities). Three of the ten major products in Shire's U.S. drug portfolio were granted priority review by FDA, based on the agency's determination that they "offer[ed] major advances in treatment, or provide[d] a treatment where no adequate therapy exists." *See* FDA, Fast Track, Accelerated Approval and Priority Review, http://www.fda.gov/ForConsumers/ByAudience/For

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[1] Pursuant to this Court's Rule 37.3(a), the amicus certifies that all parties consented to the filing of this brief. Copies of letters granting consent have been filed with the Clerk. Pursuant to this Court's Rule 37.6, the amicus certifies that no counsel for a party authored this brief in whole or in part, that no such counsel or party contributed money intended to fund the preparation or submission of this brief, and that no person other than the amicus or its counsel made such a monetary contribution. This amicus brief has been prepared and submitted to express the particular views of Shire; and it has been drafted by different attorneys from those who participated in the drafting of the amicus brief submitted on behalf of Merck & Co.

PatientAdvocates/SpeedingAccesstoImportantNewTherapies/ucm128291.htm#priorityreview. One of Shire's products has been granted Orphan Drug status and exclusivity, which is limited to drugs that treat conditions affecting fewer than 200,000 patients in the United States. 21 U.S.C. § 360bb(a)(2). Another Shire product (Elaprase®, used to treat Hunter's Syndrome) treats a condition that is estimated to affect only 1:155,000 live male births in the United States. *See* http://www.hunterpatients.com/hunter-syndrome-basics/genetics.

As a mid-size innovator pharmaceutical company, Shire has brought and settled patent infringement lawsuits against generic pharmaceutical companies under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"). Shire therefore has a strong interest in the legal standard that governs Hatch-Waxman settlements.

Shire submits this brief as an *amicus curiae* to provide the Court with the perspective of smaller and mid-size pharmaceutical companies. The risk and uncertainty created by patent infringement suits can be particularly acute for small or mid-size companies such as Shire. If Shire were unable to reduce the risk and uncertainty of Hatch-Waxman litigation through settlements, it might be unable to continue investing in challenging research and development projects, including the development of new drugs for rare diseases.

SUMMARY OF ARGUMENT

There are valid and procompetitive reasons for innovator companies to settle Hatch-Waxman litigation. In particular, small and mid-size innovator companies face strong pressure, unrelated to any anticompetitive motive, to settle Hatch-Waxman litigation. When Hatch-Waxman litigation concerns a product that represents a large percentage of the company's total revenues, it can create a cloud of uncertainty over the entire company. This uncertainty causes disruption to the innovator company's business, and may cause it to cut back on investments in research and development. Settlements that reduce uncertainty generally benefit consumers, and should not be presumptively unlawful. If innovator companies are limited to negotiating over a generic entry date, procompetitive settlements may not occur.

Innovator companies may also settle Hatch-Waxman cases because they are sensitive to the risk of a litigation loss. A small or mid-size company facing a litigation challenge to its flagship product may be risk-sensitive even if the company concludes that it is likely to prevail in the litigation. If risk-sensitive innovators are limited to negotiating over a generic entry date, they could be obliged to surrender a substantial percentage of the perceived value of their patents in order to avoid the risk of a complete loss in litigation. This, in turn, would make innovator companies less willing to invest in developing new drugs.

ARGUMENT

Innovator Companies, Especially Small and Mid-Size Companies, Have Procompetitive Reasons To Settle Hatch-Waxman Litigation.

Innovator companies have valid reasons to settle Hatch-Waxman litigation that are unrelated to any effort to suppress competition. The pressures to reach a settlement are likely to be especially strong for smaller companies that are heavily dependent on revenues from one or two products. Such settlements may benefit consumers by ensuring that generic drugs are brought to market more quickly, without unduly discouraging investments in developing new drugs. For these reasons, the Federal Trade Commission's proposal to treat all payments by the pioneer company as "presumptively unlawful" if they are part of a Hatch-Waxman settlement sweeps too broadly. Rather, the scope-of-the-patent test should be used to evaluate these settlements.

Because one or a few drug products may represent a substantial percentage of a small to mid-size company's total revenues, Hatch-Waxman litigation concerning these products creates a cloud of uncertainty over the entire business. The consequences of losing the litigation may be devastating to the innovator. As a result, the pressure to settle is extremely high, regardless of the strength of the underlying patents. Even if the innovator believes it will ultimately prevail in the litigation, it faces significant loss of opportunities

and disruption to its businesses while the litigation is pending.

If such companies are effectively limited to negotiating over an entry date, they may not be able to reach a settlement. *See, e.g.*, Solvay Br. 32 ("[I]f the generic company has to wait 10 years before entry, it might require additional compensation given the risk that the market might shift to another drug in that time, or that it would not be operating under the same corporate ownership by then, or because its management compensation is based on short-term profits."). Even if the parties are able to reach a settlement based solely on a generic entry date, the loss of valuable patent rights may significantly reduce the innovator company's incentives to continue making large investments in challenging research and development.

The FTC recognizes that there are "possible legitimate justifications . . . or procompetitive potential" for settlements that include payments from the innovator company to the generic company, FTC Br. 33, but the agency nevertheless argues that such settlements should be "presumptively unlawful," *id.* at 19, and that the parties should bear a "heavy burden of establishing an affirmative defense," *id.* at 37 (quoting *NCAA v. Bd. of Regents of the Univ. of Okla.*, 468 U.S. 85, 113 (1984) (internal quotation marks omitted)). As the FTC acknowledges, even apart from the rights conferred by a patent, "[t]he rule of reason is the accepted standard for testing whether a practice restrains trade in violation of [Sherman Act] § 1." FTC Br. 33 (quoting *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 885 (2007) (internal quotation marks omitted)).

A presumption of illegality is appropriate only when "a confident conclusion about the principal tendency" of a practice can be drawn. FTC Br. 34 (quoting *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 781 (1999) (internal quotation marks omitted)). No such "confident conclusion" can be drawn here. To the contrary, the Court should continue to apply the "scope-of-the-patent" test that has governed patent-related restraints for decades. *See, e.g.*, Solvay Br. 14-16.

A. Innovator Companies Settle Hatch-Waxman Litigation To Minimize Uncertainty.

This Court has recognized that "the potential for uncertainty and disruption in a lawsuit could allow [parties] with weak claims to extort settlements from innocent companies." *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 163 (2008); *see also Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007); *Coopers & Lybrand v. Livesay*, 437 U.S. 463, 476 (1978). The potential for uncertainty and disruption, and the resulting pressure to settle even weak claims made by generic companies, frequently arises in Hatch-Waxman litigation. It arises in a particularly strong form when a small or mid-size innovator company is faced with a Hatch-Waxman challenge to a product that represents a large percentage of the company's total revenues. *See* Bret Dickey, Jonathan Orszag, & Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 Annals Health L. 367, 382 (2009-10) ("[F]or some brand-name manufacturers, the financial health of the company may depend importantly on the success of a single

drug line."); Erin Coe, *Growth of Specialty Pharma Draws Generics Litigation*, Law 360 (Dec. 3, 2007), http://www.law360.com/mergersacquisitions/articles/41450/growth-of-specialty-pharma-draws-generics-litigation ("Generic competition poses a threat to specialty pharmaceutical companies," because these companies "are often dependent on a particular product") (internal quotation marks omitted). Because small and mid-size innovator companies often have the most to lose in Hatch-Waxman litigation, they often have particularly strong incentives to reach a settlement.

As this Court has noted, "[t]he very pendency" of litigation "may frustrate or delay normal business activity of the defendant." *Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 739 (1975). In the Hatch-Waxman context, "[t]he length of patent litigation may itself impose costs on the patentee by making marketing, research and development, and other business planning difficult while the outcome of the case remains uncertain." *See* Daniel A. Crane, *Ease Over Accuracy in Assessing Patent Settlements*, 88 Minn. L. Rev. 698, 704 (Feb. 2004). Innovator companies—particularly smaller companies with limited resources—may be forced to cut back on investments in new products. *See Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1075 (11th Cir. 2005) (The "caustic environment of patent litigation may actually decrease product innovation by amplifying the period of uncertainty around the drug manufacturer's ability to research, develop and market the patented product."); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 203 (2d Cir. 2006) ("Rules severely restricting patent settlement

might also be contrary to the goals of the patent laws because the increased number of continuing lawsuits that would result would heighten the uncertainty surrounding patents and might delay innovation."). In addition, the innovator company's plans for marketing its flagship product, as well as other products, may be severely disrupted by high-stakes Hatch-Waxman litigation.

Investors also dislike uncertainty. *See* Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles*, 15 Fed. Cir. B.J. 617, 626 (2005) ("The impact of uncertainty on investment decisions is well known."). When a small or mid-size pharmaceutical company faces Hatch-Waxman litigation, it may have difficulty raising capital for new projects. The uncertainty created by the litigation may cause the company's stock price to fall or become more volatile, further disrupting the company's business.

Even if the innovator company is relatively confident that it will prevail in the litigation, litigating a Hatch-Waxman case (or series of cases) to a final conclusion can take years and cost millions of dollars. In the meantime, the uncertainty created by the litigation may cause a smaller innovator company to lose important opportunities that can never be recovered.

There is no reason for antitrust law to prohibit settlements that reduce uncertainty. As a general matter, such settlements are likely to benefit, rather than harm, consumers. *See* Xiang Yu & Anjan Chatterji, *Why Brand Pharmaceutical Companies Choose to Pay Generics in Settling Patent Disputes: A*

Systematic Evaluation of the Asymmetric Risks in Litigation, 10 Nw. J. Tech. & Intell. Prop. 19, 32 (Nov. 2011) ("Allowing the brand to settle will dispel . . . uncertainties and help restore adequate marketing activities, maximizing non-price competition benefits to consumers."). Indeed, Shire has entered into settlements that have ensured the entry of generic versions of Shire's products years before the patents-at-issue are to expire, and before the generic companies have been able to gain FDA approval on their own.

In order to reach a settlement, innovator companies and generic companies may enter into a variety of business arrangements, including licensing agreements for other products, co-promotion agreements, research and development agreements, and supply agreements concerning raw materials. The FTC argues that such arrangements should be treated as "presumptively illegal" under the antitrust laws. *See* FTC Br. 11-12. But since such arrangements frequently are based on a desire to minimize uncertainty rather than any anticompetitive motive, there is no basis for imposing such a sweeping rule of illegality. *See also* Solvay Br. 41-45. Indeed, a legal standard that treated ordinary business arrangements as presumptively unlawful would deter procompetitive settlements and discourage innovative companies from making investments in challenging research and development.

B. Innovator Companies Settle Hatch-Waxman Litigation Because They Are Sensitive to Risk.

Innovator companies—particularly small and mid-size companies—have an additional valid reason to settle Hatch-Waxman litigation: heightened sensitivity to risk. If an innovator company places a high value on avoiding the risk that it will lose the patent infringement case, it will be willing to enter into a settlement that is more favorable to the generic company than a settlement based solely on the parties' views of the merits of the litigation. *See* Yu & Chatterji, *supra*, at 21 ("The brand is often risk-averse and has every desire to settle the uncertainty, even if it has strong defenses for the patent's validity, because it has so much to lose and nothing to gain."). Such a settlement is not based on an anticompetitive motive, nor does it reflect inherent weakness in the patents. Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. Econ. 391, 408 (2003) (settlement payments may not be anticompetitive "if other factors are brought into the analysis, such as risk aversion and asymmetric information about market conditions, as 'reverse cash payments' may be important in more complex settings for successful settlement."); Solvay Br. 28 ("[T]he government itself has previously recognized . . . that 'gross disparities in the litigants' respective risks may . . . make reverse payments

more likely, even when the patentee's legal claims are strong.'" (internal citations omitted)).[2]

As commentators have noted, a small or mid-size pharmaceutical company faced with a litigation challenge to its flagship product is likely to be highly sensitive to litigation risk. *See* Butler & Jarosch, supra n.2, at 96 (increased risk aversion "likely to be found in firms that rely on a single patent for much of their business and is less likely to be present in firms that have diversified sources of income"). Just as a risk-averse individual will pay extra to avoid a relatively small risk of death, a risk-averse company will pay to avoid the risk that it will be destroyed by the litigation. *See* Sumanth Addanki & Alan J. Daskin, *Patent Settlement Agreements*, 3 ABA Section of Antitrust Law, Issues in Competition Law & Policy 2127, 2131 (2008) ("[W]hen choosing between a settlement and pursuing litigation to its final outcome, the patentee would recognize that the nonzero probability associated with 'losing it all' creates very real risk, regardless of the expected value associated with litigation."); *see also Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1310 (11th Cir. 2003) ("[G]iven the asymmetries of

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[2] *See also* Henry N. Butler & Jeffrey Paul Jarosch, *Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation*, 96 Iowa L. Rev. 57, 95 (Nov. 2010) ("[E]ven reverse payments that are larger than avoided litigation costs may, if the patent holder is very risk averse, not be payments for delay, but rather payments to avoid the risk that the patent will be held invalid.").

risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement."); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 208 (E.D.N.Y. 2003) ("Even the confident patent owner knows that the chances of prevailing in [patent] litigation rarely exceed seventy percent. . . . Thus, there are risks involved even in that rare case with great prospects.") (citation and internal quotation marks omitted).[3]

If a risk-sensitive innovator were limited to negotiating a generic entry date, the innovator could remove the risk of Hatch-Waxman litigation only by permitting generic entry significantly before the innovator's patent expires. A small or mid-size company that is dependent on revenues from one or

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[3] There are other reasons for innovator companies to be litigation risk-averse. For example,

> the firm may have invested considerable sums in research and development to obtain the patent with assurances to shareholders of a profitable return on the investment. An unexpected loss of the patent lawsuit may cause management to lose credibility with shareholders and lead to a greater decline in the value of the company's shares than the lost net present value of future monopoly profits from winning the patent case. Settling allows management to eliminate the possibility of unexpected bad news that might have wider ripple effects for the firm.

Crane, *supra*, at 704-05 (internal footnote omitted).

two products might choose such an unfavorable settlement over the protracted uncertainty of patent litigation. As a result, the FTC's proposed rule would foster "an environment in which risk-averse patent holders receive relatively little value from their patents, because upon challenge, they must give up much of the life of that patent in settlements that may not include reverse payments." Butler & Jarosch, *supra* n.2, at 95-96; *see also* Bernard & Tom, *supra*, at 631 ("[S]ettlements without cash side payments . . . may be systematically skewed toward giving the patent owner a shorter period of exclusivity than the perceived probabilities warrant.").

Settlements that force the innovator company to cede a significant portion of its lawful patent rights will discourage future investments in research and development. If a company knows that it cannot afford to defend the full value of its intellectual property investment through Hatch-Waxman litigation, the company will be less likely to commit the necessary resources to bring new drugs to market. The FTC's strict rule would thus cause harm to consumers and the economy.

For all of these reasons, the FTC's rule of "presumptive illegality" sweeps too broadly. Settlement agreements in Hatch-Waxman cases may serve valid and procompetitive purposes. The need to settle such cases is likely to be particularly pressing for smaller innovator companies faced with a challenge to one of their primary products. An antitrust rule that severely restricts the parties' ability to settle such cases is not justified, and would likely cause harm to consumers.

CONCLUSION

The judgment of the court of appeals should be affirmed.

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AMICUS CURIAE BRIEF

RECORD
AND
BRIEFS

No. 12-416

IN THE

Supreme Court of the United States

FEDERAL TRADE COMMISSION,

Petitioner,

v.

ACTAVIS, INC., ET AL.

Respondents.

On Writ Of Certiorari
To The United States Court Of Appeals
For The Eleventh Circuit

BRIEF OF *AMICUS CURIAE* WASHINGTON LEGAL FOUNDATION IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

Whether a complaint alleging that lawful competition has been injured because patent litigants entered into a settlement agreement states a claim under the antitrust laws when there is no dispute that:

(1) the agreement was within the scope of the patent, in that it excluded no more competition than the claims of the patent,

(2) the patent was not procured by fraud, and

(3) the patent claim being settled was not objectively baseless.

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INTEREST OF *AMICUS CURIAE* [1]

The Washington Legal Foundation ("WLF") is a nonprofit public interest law and policy center with supporters in all 50 States. WLF regularly participates as *amicus curiae* in federal and state court proceedings to promote economic liberty, free enterprise, and a limited and accountable government. To that end, WLF has appeared in numerous cases related to patent rights and antitrust law. In particular, WLF participated as an *amicus* before the Third Circuit in *In re K-Dur Antitrust Litigation*, 686 F.3d 197 (3d Cir. 2012), and before the Eleventh Circuit in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006), a decision addressing the very same patent settlements at issue here and reached a conclusion opposite from the Third Circuit's.

WLF successfully challenged the constitutionality of Food and Drug Administration (FDA) restrictions on speech relating to off-label uses of FDA-approved drugs. *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000). WLF has also filed briefs in numerous cases involving the sort of "reverse payments" alleged to be at issue here, including proceedings in state and federal court and before the Federal Trade Commission ("FTC").

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[1] Pursuant to Rule 37.6, *amicus curiae* affirms that no counsel for any party authored this brief in whole or in part, and that no person other than *amicus* or its counsel made a monetary contribution intended to fund the preparation or submission of this brief. All parties have consented in writing to the filing of this brief.

WLF believes that both "innovator" and generic manufacturers play an important role in delivering quality health care to the American public. The antitrust standard advocated by the Petitioner here and embraced by the Third Circuit in *K-Dur* would (1) deprive the holders of drug patents of critically important legal rights that are core attributes of any patent and (2) unduly burden the efforts of generic drug makers to bring their product to market through Hatch-Waxman challenges. By contrast, the Court of Appeals below correctly applied the majority rule protecting the right of patent litigants to enter into agreements no more exclusionary than the patent itself.

WLF therefore submits this brief in support of the Respondents and urges the Court to affirm the judgment below.

PRELIMINARY STATEMENT

The Court has been asked, explicitly by the parties and implicitly by the circuit courts, to choose a standard governing the antitrust analysis of agreements that settle patent litigation concerning generic drugs. The choice is stark.

On the one hand is the so-called "scope of the patent" test, which holds that agreements within the exclusionary effect of a patent do not injure lawful competition unless the patent was procured by fraud or the infringement claim was a sham (*i.e.*, "objectively baseless"). Under this standard, the patent holder's right to exclude infringing competition is fully respected unless the antitrust plaintiff can demonstrate that the patent had no exclusionary effect at all.

This is the test of the Second, Eleventh, and Federal Circuits, applied to settlements under the Hatch-Waxman Act in six separate appellate opinions. It is the test of Judge Richard Posner, who first articulated it when sitting by designation in *Asahi Glass Co v. Pentech Pharmaceuticals, Inc.*, 289 F. Supp. 2d 989, 994 (N.D. Ill. 2003). It is the test applied by the late Judge David Trager in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d 514, 535 (E.D.N.Y. 2005) (*Cipro II*). Judge Trager was the former Dean of the Brooklyn Law School before being appointed to the bench by President Clinton, and (prior to the *K-Dur* opinion noted below) his opinions in the *Cipro* case had been cited with approval by every circuit court to address the issue of "reverse payments."[2] Indeed, the scope of the patent test is the test advocated by the most recent past General Counsel of the FTC, who concluded prior to joining the FTC that the most appropriate "proposed standard is the sham standard [of] Judge Posner [in *Asahi Glass*]." Kent S. Bernard

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[2] *E.g.*, *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1313 (11th Cir. 2012); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 604 F.3d 98, 106 (2d Cir. 2010) (affirming Judge Trager), *cert. denied*, 131 S. Ct. 1606 (2011); *In re Ciprofloxacin Hydrochloride Antitrust Lit.*, 544 F.3d 1323, 1336-37 (Fed. Cir. 2008) (affirming Judge Trager), *cert. denied*, 557 U.S. 920 (2009); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006), *cert. denied*, 551 U.S. 1144 (2007); *Schering-Plough*, 402 F.3d at 1068; *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F. 3d 1294, 1304 (11th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004); *cf. In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 907-08 nn.12-13 (6th Cir. 2003) (approving Judge Trager's conclusion that the settlement in *Cardizem*, unlike *Cipro*, imposed restraints beyond the exclusionary effect of the patent).

& Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles*, 15 Fed. Cir. B.J. 617, 632 (2006) ("Bernard & Tom").

On the other hand is the standard of presumptive illegality advocated here by the Solicitor General and the FTC ("the Government"). Under this test, any Hatch-Waxman settlement with "payments" to the generic challenger is presumptively anticompetitive. Under this test, the patent holder's right to exclude infringing competition plays no role whatsoever: the presumption applies whether or not the generic drug was infringing, and it may *not* be rebutted by any showing of actual infringement. (PB 37-39, 53-55.)

In contrast to the scope of the patent test, this "presumptive liability" test is that of a single circuit court, that is, the Third Circuit in *K-Dur*. It is a test that the FTC has advocated by supplying differing and inconsistent rationales since it lost on appeal in *Schering-Plough*, 402 F.3d 1056. This is the test that the Solicitor General has described, on at least three prior occasions when asked by the Court to address this issue, as bad law and bad policy: "[T]he public policy favoring settlements, and the statutory right of patentees to exclude competition within the scope of the patent, would potentially be frustrated by a rule of law that subjected patent settlements involving reverse payments to automatic *or near-automatic* invalidation." U.S. Br. at 10-11, *Schering-Plough*, 548 U.S. 919 (2006) (No. 05-273) ("*Schering-Plough* Br."). That was when the Solicitor General described as erroneous "the FTC's view [that] the presence of a reverse payment ... has necessarily rendered consumers worse off and lessened competition ...." *Id.*

at 12. This, then, is a test of antitrust law that would render what the Solicitor General called the "right of patentees to exclude competition within the scope of the patent," *id.* at 10-11, a dead letter.

STATEMENT OF THE CASE

AndroGel is a testosterone replacement medication used to treat hypogonadism. (J.A. 28, at ¶¶ 31-33.). Respondent Solvay Pharmaceuticals, Inc. ("Solvay") controls the patent rights relating to AndroGel. The principal patent at issue here, the '894 patent, issued in January 2003 and expires in August 2020. (J.A. 39.)

In May 2003, Respondent Actavis, Inc., then known as Watson Pharmaceuticals, Inc., filed an Abbreviated New Drug Application ("ANDA") with the FDA pursuant to the Hatch-Waxman Act. *See* Drug Price Competition and Patent Term Restoration [Hatch-Waxman] Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of Titles 15, 21, and 35 U.S.C.). The ANDA requested approval to market a generic version of AndroGel. (J.A. 39.) Because Watson also sought to enter the market prior to the expiration of the '894 patent, it included a "Paragraph IV" certification stating that its product would not infringe the patent. (*Id.*)

A second generic applicant, Respondent Paddock Laboratories, Inc., filed another "ANDA IV" as to AndroGel shortly afterward. (J.A. 39.) Paddock would later partner with Respondent Par Pharmaceuticals Companies, Inc. in exchange for distribution rights as to its generic Androgel product. (J.A. 40.)

Solvay's predecessor filed suit in August 2003 for infringement of the '894 patent against both generic companies. (J.A. 40.) Because it did so within 45 days of being notified of the ANDAs, Solvay received an automatic 30-month stay during which the FDA could not finally approve either ANDA.

After three years of litigation, the parties settled the cases in September 2006. The agreements gave both generic challengers the right to launch their products in August 2015, five years before the '849 patent expires. (J.A. 46, 49.)

The settlements also included separate agreements for promotional and manufacturing services. Watson agreed that its sales force would promote AndroGel to urologists, and Solvay agreed to pay Watson a portion of such sales. (J.A. 45.) Par agreed to promote AndroGel to primary care physicians until 2012 in exchange for $10 million annually. (J.A. 49.) Paddock agreed to provide Solvay with backup manufacturing capacity until 2012 in exchange for $2 million annually. *Id.* The total payments by Solvay amounted to less than 10% of its AndroGel revenues at the time. (J.A. 28.)

After two years of investigation, the FTC filed suit against the settling parties. The complaint alleged that the separate agreements were not "independent" transactions, because Solvay overpaid for the services. (J.A. 50-53.) That "payment" allegedly caused the generic parties to accept a later entry date than they would have otherwise. (*Id.*) The FTC also alleged the patent holder was "not likely to prevail" in the patent suits. (J.A. 53.) The FTC did not allege that the settlement went beyond the scope of the patent,

that the patent was procured by fraud, or that the patent claim was objectively baseless.

The district court dismissed the FTC's complaint, rejecting the argument that settlements with reverse payments should be presumptively unlawful. (Pet. App. 51a.) The Eleventh Circuit affirmed, applying its "scope of the patent" test, which provides that, in the absence of procurement fraud or sham litigation, a settlement within the scope of a patent cannot injure competition. (Pet. App. 17a.) The circuit court also rejected the allegation that the patent was "likely" to fail, noting that "it is simply not true that an infringement claim that is 'likely' to fail actually will fail." (Pet. App. 30a.)

Shortly after the Eleventh Circuit ruled, a panel of the Third Circuit issued its *K-Dur* opinion. 686 F.3d 197. *K-Dur* accepted the FTC's proposed standard and held that Hatch-Waxman settlements with reverse payments are presumptively illegal. The court expressly rejected the scope of the patent test of the other circuits and stated that, in performing the antitrust analysis, "there is no need to consider the merits of the underlying patent suit ...." *Id.* at 218.

This Court granted the FTC's petition for certiorari in this case and has not yet ruled on the petitions in *K-Dur*. Before this Court, the FTC no longer advances the theory that the generic defendant was "likely" to win, and in fact describes that test as "doctrinally anomalous and likely unworkable." (PB 53.) Instead, its proposed standard is similar to that of *K-Dur*. It would impose a presumption of illegality on all Hatch-Waxman "settlements that involve a reverse payment (or its functional equivalent) from the plaintiff to the defendant." (PB 46.) While less

than clear as to the definition of "payment" or "functional equivalent," the Government stresses that all a plaintiff need show is the presence of a reverse payment to trigger the presumption of illegality. (PB 46.) The patent merits are simply never to be considered in any attempt to rebut the presumption. (PB 37-39, 53-55.) The Government states that there are "two primary ways in which the parties to a reverse-payment settlement ... could rebut the presumption," (PB 37), but neither one relates to whether the generic product was infringing and hence unlawful. Under this proposed test, like the Third Circuit's test, "the merits of the underlying patent suit" are of no consequence. *K-Dur*, 686 F.3d at 218. The patentee's right to exclude is simply excluded.

SUMMARY OF ARGUMENT

I. The test of presumptive illegality advanced by the Government here lacks any support in this Court's decisions, in antitrust and patent policy, or in simple logic. Two fundamental fallacies in the Government's reasoning demonstrate why.

A. The first is the failure to recognize that the patent holder's right to exclude infringing competition is not merely the central question in the analysis — it is the *only* reason why virtually all patent settlements and patent licenses do not fit the definition of per se illegal market division agreements. *E.g.*, XII Herbert Hovenkamp, *Antitrust Law* ¶ 2040b (2d ed. 2005) ("[Licensing] agreements would generally be classified ... as per se unlawful naked horizontal market divisions" in the "absence of a patent.") (footnote omitted)); *see also Valley Drug*, 344 F.3d at 1304 ("This is not ... a case [of market

division], however, because one of the parties owned a patent.").

This point dooms any attempt to articulate a standard — such as the one the Government advances — that neither includes nor accounts for the patent holder's potential ability to exclude the generic product as infringing. Because the antitrust laws do not protect unlawful competition, the controlling question is whether the competition being "excluded" is infringing and should be kept out, or is non-infringing and should be allowed in. In the antitrust analysis, the amount of consideration paid or the direction in which it flowed is wholly irrelevant. Unless the antitrust plaintiff demonstrates that the allegedly excluded competition was lawful, there is no effect on competition no matter how much was paid. On the other hand, if the patent claim was objectively baseless and the generic product non-infringing, the patentee could hardly defend the settlement by claiming that it did not pay much cash for it.

This point also exposes the error in the Government's repeated claims that a "quick look" analysis or some other heightened form of scrutiny is proper here because a reverse payment settlement "resembles" a market division agreement. (PB 15, 19-20, 34-35.) If we ignore the patent right, the resemblance is not simply strong, but virtually perfect. But add the patent right, and there is no meaningful resemblance at all. The crucial difference is the underlying legal right to engage in the conduct. If one adopts a standard that ignores that right, there will be nothing to take a "quick look" at.

B. The second fallacy in the Government's analysis is its false assumption that, when parties to

a Hatch-Waxman dispute negotiate a settlement, only the position of the generic challenger corresponds to the competitive interest of consumers. (PB 28.) But that simply assumes the answer to the very question being litigated and settled. If we knew in advance that the patent holder would lose the patent case, the Government's assumption might hold. But it is equally true that, if we knew the patentee would win, the competitive interest of consumers would be precisely the opposite. If the generic product would infringe a valid patent, consumers would *suffer* by early generic entry, as their competitive interest in innovation would be diminished. Bernard & Tom, *supra*, 15 Fed. Cir. B.J. at 622 ("[I]f the settlement prevents infringing entry, such prevention in itself is a *pro-competitive* effect." (emphasis added)).

It is simply not true that all consumers prefer the short-run benefits of lower generic prices to the long-run benefits of newly discovered, life-saving drugs. Only by adopting this one-sided and unsupported view of the consumer's competitive interest can the Government articulate any theory of competitive harm.

Even granting its false assumption, however, the Government's test remains logically and legally flawed. The Government concedes that not all cases can be settled with the "ideal" term-splitting settlement it imagines. Because parties to these settlements place very different values on the duration of any license, there is often no specific entry date that both can accept. Likewise, differing assessments of the strength of the patent claim and differing attitudes toward risk aversion — factors

that the Government simply ignores — show that other consideration, such as cash, is often necessary to bridge the settlement gap. The Government's response, that parties in such a situation should be forced to litigate to judgment rather than settle, describes a competitive interest unknown to antitrust.

Legally, of course, the potential existence of a settlement the Government deems "more "competitive" is not sufficient to show that the settlement actually reached was unreasonable. *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 415-16 (2004) ("The Sherman Act ... does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition." (internal quotation marks and citation omitted)). Patent litigants "who wish only to settle the present litigation" are not required "to act as unwilling private attorneys general" for consumers — or at least those consumers that the Government seems to prefer. *Nestle Co. v. Chester's Market, Inc.*, 756 F.2d 280, 284 (2d Cir. 1985).

II. The test advanced by the Government would accomplish a radical revision to established antitrust and patent law principles. This Court's decisions have, for well over a century, acknowledged and protected the right of patent holders to enter into agreements no more exclusionary than the patent itself. The Government offers no limiting principle to its theory, which would distinguish patent licenses entered into outside of litigation from licenses entered into in settlement of litigation. The test advanced would thus endanger all such agreements,

including commonplace license terms widely used since the Constitution was adopted.

The right to enter into agreements concerning the use of a patented invention on any terms that do not extend the patent's scope is one of the oldest and most secure of all patent rights. *E.g.*, *United States v. Gen. Elec. Co.*, 272 U.S. 476, 489 (1926) ("[T]he patentee may grant a license ... for any royalty or upon any condition the performance of which is reasonably within the ... patent ...."). This Court's decisions establish that a patentee may grant a single license, many licenses, or none at all. Yet the Government argues that the parties to a Hatch-Waxman suit not only *must* grant a license in settlement, but a license that is as long as the "ideal" term-splitting license it posits.

This Court's decisions further establish that a patentee may restrict its license by telling the licensee when it may sell, where it may sell, to whom it may sell, and how much it may sell. Yet the Government's theory would impose treble damages on the parties to a Hatch-Waxman suit if they include *any* term in the license other than the generic challenger's entry date. The Government provides no theory of competitive harm remotely justifying this proposal "to work a revolution in patent law." *Cipro II*, 363 F. Supp. 2d at 529.

Nor will the Government's test be limited to actual payments. The FTC recently attempted (without success) to persuade two district courts in the Third Circuit that Hatch-Waxman settlements that include exclusive licenses (or that convey to the generic party anything of "value") should be deemed for that reason to contain "reverse payments" within the meaning of

the *K-Dur* decision. This further demonstrates that the Government's standard has no limiting principle. Just as it cannot be limited to settlements, as opposed to licenses, it cannot be limited to payments, as opposed to other classical license terms.

III. As dangerous as the Government's standard is for routine patent agreements, it inflicts even more harm in the context of settlement. After all, settlement agreements produce a variety of independent pro-competitive effects that should make the Court even less receptive to the Government's attempt to redefine competition here. Settlements promote consumer welfare and conserve judicial resources to such a degree that one treatise has suggested that "some agreements that would be unlawful if undertaken in the absence of a reasonable dispute may be lawful when used to settle a bona fide [patent] dispute." XII Hovenkamp, *supra*, ¶ 2046, at 309.

The Government's implication that Congress somehow limited the rights of parties to Hatch-Waxman suits to settle cannot be supported. There is no indication in the statute or its enactment history that Congress intended the rules affecting patent litigation to change — just the opposite. It defies credulity to argue that, in setting up a process that expressly included patent *litigation*, Congress also intended to work a fundamental and unprecedented restriction on the right to settle without saying so. *Cf. Am. Bar Ass'n v. Fed. Trade Comm'n*, 430 F.3d 457, 467 (D.C. Cir. 2005) ("Congress does not ... hide elephants in mouse holes." (quoting *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001))).

ARGUMENT

The parties and other *amici* have demonstrated that the scope of the patent test is firmly grounded in this Court's decisions, such as *Bement v. National Harrow Co.*, 186 U.S. 70 (1902), *Standard Oil Co. v. United States*, 283 U.S. 163 (1931), and *Walker Process Equipment, Inc. v. Food Machinery & Chemical Co.*, 382 U.S. 172 (1965). (*See, e.g.*, Par/Paddock Br. at 39-44 (discussing *Standard Oil*); *id.* at 46-51 (discussing *Walker Process*).) None of these decisions was mentioned by the Third Circuit in *K-Dur*, and none are discussed by the Government here. The focus of this discussion is not on the test properly applied below, but on the Government's proposed standard. Here, we analyze the false premises from which it proceeds (Section I) and the dire consequences it portends for the conduct of business concerning patents (Sections II & III).

I. THE GOVERNMENT'S ATTEMPT TO JUSTIFY A STANDARD OF PRESUMPTIVE ILLEGALITY RESTS ON TWO ESSENTIAL FALLACIES

A. The Legality Of Agreements Concerning Patent Rights Depends Fundamentally On The Patentee's Right To Exclude.

As shown above, the Government's proposed standard completely ignores the right of the patent holder to exclude infringing competition. (*Supra*, pp. 7-8.) That essential right is not considered at all in imposing the presumption of illegality, nor deemed relevant to any attempt to rebut it. (*Id.*) The Government's proposal is not only unprecedented,

but unmoored to any concern grounded in *competition* policy.

The core fallacy in any antitrust standard that ignores patent rights is this: the patent holder's right to exclude infringing competition is not merely the central question in the analysis — it is the *only* reason why virtually all patent settlements and patent licenses do not fit the definition of per se illegal market division agreements. XII Hovenkamp, *supra*, at ¶ 2040b ("[Licensing] agreements would generally be classified ... as per se unlawful naked horizontal market divisions" in the "absence of a patent." (footnote omitted)); *see United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1128 (D.C. Cir. 1981) ("[A] patent by definition restrains trade, and in effect makes most exclusive patent licenses per se violations of the antitrust laws.").

The existence of the patent, and the right it grants to exclude infringers, controls the antitrust analysis for a simple reason. The antitrust laws do not protect unlawful competition, [3] including products that infringe a patent: "[T]he public [i]s not entitled to profit by competition among infringers." *Rubber Tire*

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[3] *In re Canadian Import Antitrust Litig.*, 470 F.3d 785, 790-92 (8th Cir. 2006) (finding no antitrust liability for precluding illegal importation of drugs); *see also, e.g., RSA Media, Inc. v. AK Media Group, Inc.*, 260 F.3d 10, 15 (1st Cir. 2001) (holding that because RSA was legally ineligible to compete, "[a]ny injury suffered by RSA is therefore unrelated to AK's allegedly exclusionary conduct ...."); *Access Telecom, Inc. v. MCI Telecomms. Corp.*, 197 F.3d 694, 712-13 (5th Cir. 1999) ("If there is no legal U.S. export market ..., then there is no antitrust injury.").

Wheel Co. v. Milwaukee Rubber Works Co., 154 F. 358, 364 (7th Cir. 1907); *Hynix Semiconductor Inc. v. Rambus Inc.*, 527 F. Supp. 2d 1084, 1096 (N.D. Cal. 2007) ("[A]n infringer" has "no legal right to be competing in the product market."); *Monarch Marking Sys., Inc. v. Duncan Parking Motor Maint. Co.*, No. 82C2599, 1988 WL 5038, at *5 (N.D. Ill. Jan. 19, 1988) ("Neither [plaintiff] nor consumers have a right to the sale of labels which infringe Monarch's patents."), *partially vacated on other grounds*, 1988 WL 23830 (N.D. Ill. Mar. 8, 1988); Richard A. Posner, *Economic Analysis of Law* 91 (5th ed. 1998) ("We do not want an efficient market in stolen goods.").

The controlling question is whether the competition being "excluded" is infringing and should be kept out, or is non-infringing and should be allowed in. Even former Commissioner Leary, the author of the FTC's *Schering-Plough* opinion, conceded that actual competitive harm could not be divorced from the merit of the patent claim: "If a patent is valid, the pioneer manufacturer is entitled to its monopoly profit, and a settlement that merely transfers a portion of that profit to a potential generic manufacturer *causes no harm*." Thomas B. Leary, *Antitrust Issues in Settlement of Pharmaceutical Patent Disputes*, 14 ABA Antitrust Healthcare Chron. 1, 6 (Winter 2000/2001) (emphasis added).

The Eleventh Circuit thus explained in *Valley Drug* that, in evaluating a Hatch-Waxman settlement, the patent makes all the difference:

> If this case merely involved one firm making monthly payments to potential competitors in return for their exiting or refraining from entering the market, we

> would readily affirm the district court's order. *This is not such a case, however, because one of the parties owned a patent.*

344 F.3d at 1304 (emphasis added). What matters to the antitrust inquiry is the character of the allegedly excluded competition, not the consideration paid or the direction in which it flowed. *Id.* at 1309 ("The failure to produce the competing ... drug, rather than the payment of money, is the exclusionary effect."). If the antitrust plaintiff cannot demonstrate that the allegedly excluded competition was lawful, there is no effect on competition no matter how much was paid. On the other hand, if the generic product were known to be non-infringing, the patentee could hardly defend the deal by pointing out that the consideration was something other than cash. In all but the rarest cases, the only justification can be that the licensee had no independent right to be in the market — because of the patent.[4]

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[4] As the Respondents have demonstrated in their merits briefs, this point makes the scope of the patent test the only one that properly accounts for the patentee's right to exclude. (*E.g.*, Solvay Br. at 38-41.) The tools of antitrust litigation will allow a court to measure with appropriate confidence whether a claim was objectively baseless or not. Beyond that, an attempt to "relitigate" the patent case in a later antitrust case is not only speculative, *Whitmore v. Arkansas*, 495 U.S. 149, 159-60 (1990) ("It is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case."), but pointless. When, as here, the claim was brought in good faith (*i.e.*, with probable cause), we already know that either side could have won. Having a later antitrust jury pick a winner on a given date adds nothing to the antitrust analysis. By definition, another jury could reasonably disagree. "It is not 'bad faith' ... to assert patent rights that one is not certain will be upheld in a suit for infringement pressed to judgment and to

The D.C. Circuit recognized the flaw in the Government's approach decades ago in *Studiengesellschaft*, 670 F.2d 1122. There, because the district court conducted a rule of reason analysis that gave no weight to "the scope of patent protection, ... its method of analysis had the effect of applying a per se rule." *Id.* at 1128. But that simply dictated an erroneous outcome: "[O]nce the protection of the patent was removed, the license conditions, like the patent itself, inevitably had the effect of restricting competition." *Id.*

This point reveals the error in the Government's repeated claims that a "quick look" analysis or some other heightened form of scrutiny is proper here because a reverse payment settlement "resembles" a market division agreement. (PB 15, 19-20, 34-35.) If the right to exclude is deemed irrelevant, that resemblance is quite striking. But add the patent right, and there is no meaningful resemblance at all. The Government's repeated citation to *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46 (1990) (PB I, 20, 24), actually illustrates its error. There, the parties were *current* competitors who agreed to divide their market. There was no suggestion that anyone's intellectual property rights precluded competition in any way. The subsequent agreement allowed one of the parties to use the other's trademark, but they had competed for years without any such provision. *Id.* at 48-49. Thus, saying that a patent settlement with payments resembles the agreement in *Palmer* is like

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settle the suit to avoid risking the loss of the rights. No one can be *certain* that he will prevail in a patent suit." *Asahi Glass*, 289 F. Supp. 2d at 993 (original emphasis).

saying that a soldier's firing his weapon in battle resembles the act of an assassin and so should be presumed unlawful. The crucial difference is the underlying legal right to engage in the conduct.

"Quick look" antitrust scrutiny applies only where "the great likelihood of anticompetitive effects can be easily ascertained," or "a confident conclusion about the principal tendency of a restriction may be drawn." (PB 34 (quoting *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 770-71 (1999)). That condition obviously cannot be met when, without accounting for the question of infringement, we do not know that the settlement threatened competition at all.

B. The Government's One-Sided Concept Of The Consumer Interest In Patent Settlements Is Unsupported And Wrong

1. There can be no antitrust claim without an injury to competition. "The law directs itself not against conduct which is competitive, ... but against conduct which unfairly tends to destroy competition itself." *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993). In attempting to articulate a theory of harm to competition that ignores the patent right, the Government imagines an ideal settlement in which the patent litigants negotiate over one term only, *i.e.*, "a compromise date of generic entry." (PB 27.)

But the Government must also concede that, if the patent is to be ignored, this ideal term-splitting license would also be a market division agreement. (PB 27-28 ("[S]uch a compromise settlement of paragraph IV litigation will entail the parties' agreement not to compete ....").) To solve that

problem, the Government offers a rationale that redefines the meaning of competition. It argues that a settlement negotiation limited to a generic entry date "has the practical effect of aligning [the generic's] interests in paragraph IV litigation with that of consumers, who benefit from the lower prices that generic competition provides." (PB 28.)

This assumption — that when parties to a Hatch-Waxman dispute negotiate a settlement, only the position of the generic challenger corresponds to the competitive interest of consumers — is false. Indeed, it simply assumes the answer to the very question being litigated and settled. If we knew in advance that the patent holder would lose the patent case, the Government's assumption might hold. But it is equally true that, if we knew the patentee would win, the competitive interest of consumers would be precisely the opposite. If the generic product would infringe a valid patent, consumers would *suffer* by early generic entry, as their competitive interest in innovation would be diminished.

> Even in ordinary industries, the undercutting of the reward for innovation is a much more serious matter than is the loss of an opportunity for price reductions.... Judge Easterbrook reminded us that an antitrust policy that reduces prices today, even by a substantial amount, at the expense of a small annual reduction in the rate at which innovation occurs "would be a calamity." Pharmaceuticals, however, are no ordinary industry.

Bernard & Tom, *supra*, 15 Fed. Cir. B.J. at 623 (quoting Frank H. Easterbrook, *Ignorance and Antitrust*, in *Antitrust, Innovation, and Competitiveness* 119, 123 (Thomas M. Jorde & David J. Teece eds., 1992)).

The Government's one-sided definition of competition is insupportable, because the benefits of protecting valid patents are not simply pro-consumer, but *pro-competitive*. *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 876 (Fed. Cir. 1985) (recognizing the right to exclude infringers "serves a very positive function in our system of competition"); Charles F. Rule, *Patent-Antitrust Policy: Looking Back and Ahead*, 59 Antitrust L.J. 729, 730 (1991) (stating that the existence and protection of patent rights "driv[e] economic growth and increas[e] consumer welfare.") As a result, the exclusion that accompanies a settlement may just as easily be characterized as procompetitive (for excluding potentially infringing entry) as anticompetitive (for excluding potentially non-infringing entry). Bernard & Tom, *supra*, 15 Fed. Cir. B.J. at 622 ("[I]f the settlement prevents infringing entry, such prevention in itself is a pro-competitive effect."). As the Solicitor General once told this Court, "legitimate patent settlements ... further the important goals of encouraging innovation and minimizing unnecessary litigation." U.S. Br. at 8-9, *Tamoxifen*, 551 U.S. 1144 (2007) (No. 06-830) ("*Tamoxifen* Br.").

The Government's brief pays lip service to this procompetitive effect, (PB 45 ("[P]reserv[ing] the incentives to innovate ... benefit[s] consumers in the long run.")), but it finds no place in the Government's one-sided definition of consumer harm. The FTC's

former General Counsel has pointed out the flaw in this approach: "It is inappropriate to use an analytical model in which the benefits of price competition on one side of the equation are taken into account, but the benefits of innovation on the other side of the equation are not." Bernard & Tom, *supra*, 15 Fed. Cir. B.J. at 621. If that mistake is made, "it is easy to get to a conclusion of presumptive illegality." *Id.* at 622.

It is simply not true that all consumers prefer the short-run benefits of lower generic prices to the long-run benefits of newly discovered, life-saving drugs. Only by adopting this crabbed view of the consumer's competitive interest can the Government articulate *any* theory of competitive harm.

2. Even with its false assumption, however, the Government's test is logically and legally flawed.

a. The Government concedes that not all cases can be settled with the "ideal" term-splitting settlement it imagines. (PB 40 ("To be sure, ... a rule discountenancing reverse payments may cause the parties to litigate to judgment.").) There are several reasons why.

Because the generic entrant will charge a lower price than the innovator charges, the parties to these settlements place highly different values on the duration of any license. Thus, there will often be no specific entry date that both can accept. *See* Mark G. Schildkraut, *Patent Splitting Settlements and The Reverse Payment Fallacy*, 71 Antitrust L.J. 1033, 1067 (2004). For example, suppose the parties are only $10 million apart in negotiations. If the generic needs six more months to generate that much extra

profit, but those six months will cost the innovator $30 million in profit, no settlement will happen. In such a case, a $10 million payment bridging that gap does not shorten the license; it makes the license possible.

In addition, differing assessments of the strength of the patent claim and differing attitudes toward risk aversion show that other consideration, such as cash, is often necessary to achieve any settlement. Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 Rand J. Econ. 391, 408 (2003) ("This is not to say that such payments are necessarily anticompetitive if other factors are brought into the analysis, such as risk aversion and asymmetric information about market conditions, as 'reverse cash payments' may be important in more complex settings for successful settlement.").

To solve this problem, the Government proposes a codicil to its already creative redefinition of competition: that the antitrust laws *prefer* that such parties should be forced to litigate to judgment rather than settle. (PB 40 ("But in the aggregate, those judgments on the merits will reflect results more in keeping with the policies of the antitrust laws, the patent act, and the Hatch-Waxman amendments than if all the cases had been settled with reverse payments.").) No authority is cited to support this curious claim, because none is available. Such a proposition is directly contrary to this Court's decision in *Standard Oil*, 283 U.S. at 171 (holding that a settlement of patent disputes "by agreement, rather than litigation, is not precluded by the [Sherman] Act."). The Government's novel

proposition thus describes a competitive "interest" unknown to antitrust.

b. The Government's preference for a pure term-splitting settlement also founders legally. Simply because the FTC deems such a settlement "more competitive" is not sufficient to show that the settlement actually reached was unreasonable. *Trinko*, 540 U.S. at 415-16 (2004) ("The Sherman Act ... does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition." (internal quotation marks and citation omitted)).[5] Accordingly, so long as the settlement excludes no more competition than does the patent itself, "consumers have no right to second-guess whether some different agreement would have been more palatable." *Cipro II*, 363 F. Supp. 2d at 536 (citing *Trinko*, 540 U.S. at 415-16); *see also, e.g.*, *Nestle Co.*, 756 F.2d at 284 (litigants, "who wish only to settle the present litigation," are not required "to act as unwilling private attorneys general" for consumers.).

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[5] *Buffalo Broad. Co. v. ASCAP*, 744 F.2d 917, 933 (2d Cir. 1984) (holding that an intellectual property license is "not even amenable to scrutiny under Section 1 unless it is a restraint of trade. The fact that it may be in some sense unnecessary does not make it a restraint."); *Am. Motor Inns, Inc. v. Holiday Inns, Inc.*, 521 F.2d 1230, 1249 (3d Cir. 1975) (rejecting least restrictive alternative test).

II. THE STANDARD OF PRESUMPTIVE ILLEGALITY HAS NO LIMITING PRINCIPLE AND THREATENS ESTABLISHED RIGHTS OF PATENT HOLDERS TO LICENSE THEIR INVENTIONS

The Government ignores the implications of its standard for patent licenses, but this Court cannot. Nowhere does the Government's brief offer any justification in logic or law for limiting its rule to settlement agreements. Nor could it. In nearly every settlement, the agreement in question contains a patent license. Whether that license came before or after a lawsuit has no impact on its propensity to injure competition.[6] As one of the commentators on which the Government relies has acknowledged, "[v]irtually every patent license can be viewed as a settlement of a patent dispute." Shapiro, *supra*, 34 Rand J. Econ. at 392. What prevents the FTC or any other plaintiff from arguing that the entry date for a license might have been earlier but for some other element of consideration, whether payments, favorable royalty rates, or field of use restrictions? Again, the Government has no answer.

Yet placing the established rights of patentees to license side-by-side with the circumscribed right to enter settlement agreements advocated here demonstrates just how radical the Government's proposed test really is. After all, the right to enter into agreements concerning the use of a patented

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[6] As we show below (see Section III), a settlement agreement may have a slightly greater tendency to *increase* competition, a point the Government also ignores.

invention on any terms that do not extend the patent's scope is one of the oldest and most secure of all patent rights. *E.g.*, *Bement*, 186 U.S. at 92 ("[A] restraint of interstate commerce [cannot] arise from reasonable and legal conditions imposed upon the ... licensee of a patent ...."); *see Studiengesellschaft*, 670 F.2d at 1129 (finding no liability where the same exclusion "would have resulted from a conventional grant of an exclusive license").

This Court's decisions establish that a patentee may grant one wholly exclusive license, many licenses, or none at all. *E.g.*, *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980); IIIB Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 772c, at 212 (3d ed. 2008) ("[R]efusal to license a patent seem[s] absolutely privileged, as does the refusal to give rivals the benefit of one's R & D."). Yet the Government argues that the parties to a Hatch-Waxman suit not only *must* grant a license in settlement, but a license that is as long as the ideal term-splitting license it posits.[7] (PB 27.)

This Court's decisions also establish that a patentee may restrict any license term that does not extend the patent: It may tell the licensee when it may sell, where it may sell, to whom it may sell, and how much it may sell. *E.g.*, *Brulotte v. Thys Co.*, 379

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[7] The Department of Justice made this point explicitly in briefs filed in the *K-Dur* litigation, stating that every settlement must allow a license of some duration. U.S. Br. as Amicus Curiae at 30, *K-Dur*, 686 F.3d 197 (3d Cir. 2012) (No. 10-2077) ("The defendants will be unable to carry their burden [of rebutting the presumption of illegality] if the settlement allowed no generic entry until patent expiration.").

U.S. 29, 33 (1964) ("A patent empowers the owner to exact royalties as high as he can negotiate with the leverage of that monopoly."); *Gen. Elec. Co.*, 272 U.S. at 489 ("[T]he patentee may grant a license ... for any royalty or upon any condition the performance of which is reasonably within the ... patent"); *see generally* 6 Donald S. Chisum, *Chisum on Patents* § 19.04[3][h] (2005) (territorial restrictions); *id.* at § 19.04[3][i] (use restrictions). Yet the Government proposes a test under which the parties to a Hatch-Waxman suit should face treble damages if they include *any* term in the license that one can argue delayed the generic challenger's entry date.

If the Court wonders why so many patent rights heretofore inviolate in the context of licenses are now to be presumptively illegal in the context of settlements, it will find no answer in the Government's brief. Judge Trager saw clearly how unlimited this presumption of illegality would be:

> If the settlement with a payment to a generic is to be subject to antitrust liability, even though it does not exceed the scope of the patent, the next antitrust challenge to a patent settlement might well take place in the context of a license with royalty .... To open royalty-bearing patent license agreements to antitrust scrutiny simply because patents are often held invalid ... would undermine the settled expectations of patentees and potential infringers/licensees across countless industries.

Cipro II, 363 F. Supp. 2d at 533. As shown above, the Government provides no theory of competitive harm

remotely justifying this proposal "to work a revolution in patent law." *Id.* at 529.

As further evidence that the Government's position has no limiting principle, the FTC has demonstrated that, if the rule of *K-Dur* is adopted, it will seek to brand classic exclusive licenses as presumptively illegal "reverse payments." When *K-Dur* was decided in July of 2012, the Third Circuit tried to limit its holding to (1) cash payments, and (2) the pharmaceutical context: "We caution that our decision today is limited to reverse payments between patent holders and would be generic competitors in the pharmaceutical industry." 686 F.3d at 216. Shortly afterward, the FTC took the unusual step of filing amicus briefs in two district courts in the Third Circuit, which were bound by *K-Dur*. There the FTC argued that the term "reverse payments" would include any consideration in an agreement that provided "value" to the generic party, including a promise to keep the license wholly exclusive by allowing no other authorized generic product. *E.g.*, FTC Br. as Amicus Curiae at 10 & n.29, *In re Lamictal Direct Purchaser Antitrust Litig.*, 2012 WL 6725580 (D.N.J. Dec. 6, 2012) (No. 2:12-cv-0995) (payment may be "money *or some other valuable thing*" (original emphasis)).[8]

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[8] This argument signaled another about-face for the FTC, which had for years insisted that monetary payments were different from other forms of consideration. "A settlement agreement is not illegal simply because it delays generic entry until some date before expiration of the pioneer's patent.... [T]he payment of money by Schering ... is what makes this case different." *In re Schering-Plough Corp.*, 136 F.T.C. 956, 987 (F.T.C. 2003), *rev'd sub nom. Schering-Plough Corp. v. FTC*, 402

Because all settlements convey value to both parties, all settlements may now run afoul of the Government's proposed rule. "*[A]ny* settlement agreement can be characterized as involving 'compensation' to the [generic] defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to be classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements." *Asahi Glass*, 289 F. Supp. 2d at 994 (original emphasis).

The *Lamictal* Court rejected the argument and refused to find that the exclusive nature of the license was a reverse payment. 2012 WL 6725580, at *6 ("[T]he term 'reverse payment' is not sufficiently broad to encompass any benefit ... to [the generic] in a negotiated settlement."). The other court declined to accept the *amicus* brief, finding the FTC too "partial" to participate. *Prof'l Drug Co. v. Wyeth Inc.*, No. 3:11-cv-05479, 2012 WL 4794587, at *2 (D.N.J. Oct. 3, 2012) ("[T]he extent to which the FTC is partial to a particular outcome weighs against granting the agency's motion.").

In sum, it is clear that the Government has articulated no limiting principle for its requested

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F.3d 1056; *see* Paying Off Generics to Prevent Competition with Brand Name Drugs: Hearing Before the S. Comm. on the Judiciary, 110th Cong. 120, 132 (2007) (prepared statement of the FTC) ("All settlements include some form of consideration flowing between the parties; *it is the type of consideration that matters* in the antitrust analysis. Some types of consideration, such as an early entry date, a royalty to the patent-holder, or compromising on a damage claim, do not generally involve sharing the benefits that come from eliminating potential competition." (emphasis added)).

standard, and that the FTC does not think any such principle necessary. The Government's rationale — that generic entry, infringing or not, is the holy grail of competition policy — does not admit one. That rationale applies as fully to other licensing terms as to payments, and as fully to licenses as to settlements.

III. NOTHING IN THE ANTITRUST LAWS OR THE HATCH-WAXMAN ACT JUSTIFIES THE GOVERNMENT'S ATTEMPT TO LIMIT THE RIGHTS OF PATENT LITIGANTS TO SETTLE

The danger to common licensing practices is not the full extent of the harm that the Government's standard portends. For there *is* a difference between settlement agreements and licensing agreements, but it cuts the other way: patent settlements have all the procompetitive benefits of patent licenses and much more. That is, settlements also produce the independent benefits flowing from the efficiencies that attend to ending litigation.

Thus, the proposition that antitrust limitations on agreements within the scope of a patent should be *more* restrictive in the context of a settlement than a license is counter-intuitive. Indeed, settlements promote consumer welfare and conserve judicial resources to such a degree that one treatise has suggested that "some agreements that would be unlawful if undertaken in the absence of a reasonable dispute may be lawful when used to settle a bona fide [patent] dispute." XII Hovenkamp, *supra*, ¶ 2046, at 309. It follows that the Government's hostility toward settlements reflected in its proposed test and arguments is not just harmful to consumers, but anticompetitive.

A. As noted, the Solicitor General has previously recognized that the fact of patent settlements alone "furthers the important goals of encouraging innovation and minimizing unnecessary litigation." *Tamoxifen* U.S. Br. at 8-9. Three such benefits bear special mention here.

First, settlements foster innovation in part because they avoid the risk of *erroneous* patent invalidation. Bernard & Tom, *supra*, 15 Fed. Cir. B.J. at 622 ("[I]f the settlement prevents infringing entry, such prevention in itself is a *pro-competitive* effect." (emphasis added)). Even Petitioner concedes that erroneous patent invalidation causes consumer harm. (*See* PB 45 ("When the brand-name manufacturer holds a strong patent, it is *likely* to prevail in litigation ... *as it should*, in order to preserve the incentives to innovate that benefit consumers in the long run." (emphasis added)).)

Second, settlements save litigants (and the public) the time and expense of trial, even if the result would have properly upheld the patent. *Bradley v. Chiron Corp.*, 136 F.3d 1317, 1322 (Fed. Cir. 1998) ("[S]ettlement reduces costs for all parties, conserves judicial and private resources, and promotes good will."); *see Marek v. Chesny*, 473 U.S. 1, 10 (1985) ("And, even for those who would prevail at trial, settlement will provide them with compensation at an earlier date without the burdens, stress, and time of litigation.").

These two reasons alone have been sufficient for the Government in the past to reject quick look scrutiny: "[T]he public policy favoring settlements, and the statutory right of patentees to exclude competition within the scope of their patents, would

potentially be frustrated by a rule of law that subjected patent settlements involving reverse payments to automatic *or near-automatic* invalidation." *Schering-Plough* Br., *supra*, at 10-11 (emphasis added).

Third, the availability of Hatch-Waxman settlements fosters more patent challenges in the long run, by reducing the generic manufacturer's costs and risks. A generic manufacturer's interest in filing a Paragraph IV challenge depends in part on having the flexibility to decide when, and on what terms, to resolve the litigation rather than engage in a multi-million dollar fight to the death in every case. *See Asahi Glass*, 289 F. Supp. 2d at 994 ("A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive."); *accord In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 256 (E.D.N.Y. 2003) ("[A] generic company should be permitted to choose not only when to commence patent litigation, but also when to terminate it. Otherwise, the incentives to mount an ANDA IV challenge could be reduced.").

B. The Government's implication that Congress somehow limited the rights of parties to Hatch-Waxman suits to settle cannot be supported. There is no indication in the statute or its enactment history that Congress intended the rules affecting patent litigation to change. Indeed, the few indications there are in the legislative history lead to the opposite conclusion.

First, it is well known that the statute had the dual purpose of promoting generic drugs while simultaneously promoting the incentives of pioneer drug companies to innovate:

> Hatch-Waxman amended both the FDCA and the patent laws in an effort to strike a balance between two conflicting policy objectives: *to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products*, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market.

aaiPharma Inc. v. Thompson, 296 F.3d 227, 230 (4th Cir. 2002) (quotation marks and citation omitted; emphasis added).

Thus, the generic entry in question was expressly intended to be *non-infringing* entry. As Congressman Waxman explained, "as a matter of public policy we, under the patent law, give that protection to the person who has put money into research and development for an innovative and new product." 130 Cong. Rec. 24,427 (Sept. 6, 1984); *see also* H.R. Rep. No. 98-857, pt. 1, at 28 (1984) ("The provisions of this bill ... are not intended to modify existing patent law with respect to the burden of proof and the nature of proof to be considered by the courts in determining whether a patent is valid or infringed.").[9]

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[9] If a later Congress had wanted to prohibit reverse-payment settlements, it could have done so. It did not do so in 2003, when it made significant changes to the statute.

It defies credulity to argue that, in setting up a process that expressly included patent *litigation*, Congress also intended to work a fundamental and unprecedented restriction on the right to settle without saying so. *Cf. Am. Bar Ass'n v. FTC*, 430 F.3d 457, 467 (D.C. Cir. 2005) ("Congress does not ... hide elephants in mouse holes." (quoting *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001))).

In sum, there is no "policy" of Hatch-Waxman that limits the rights of litigants to settle or the rights of patent holders to enter into agreements that maximize the value of a patent without extending its scope. Even if there were such a policy, it would not thereby enact a silent amendment to the *antitrust* laws. For antitrust embraces the procompetitve benefits of patents and of settlements as well as the benefits of low prices. By choosing to promote one benefit at the expense of the others, the Government's proposed standard would harm the *competitive* interest of the very consumers it pretends to champion.

Bills to ban reverse payments have been introduced in each of the last several Congresses, moreover, thus far to no avail. *E.g.*, S. 27, 112th Cong. (2011). Senator Hatch opposed a prior Senate bill to outlaw reverse payments in committee, S. Rep. No. 111-123, at 7 (2010); *id.* at 23 (bill could "effectively discourage pro-consumer settlements.")

CONCLUSION

The Court should affirm the judgment below.

Respectfully submitted,

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AMICUS CURIAE BRIEF

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Supreme Court of the United States

FEDERAL TRADE COMMISSION,

Petitioner,

v.

WATSON PHARMACEUTICALS, INC., *ET AL.*,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF OF *AMICUS CURIAE* REPRESENTATIVE HENRY A. WAXMAN IN SUPPORT OF PETITIONER

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INTEREST OF *AMICUS CURIAE*[1]

Representative Henry A. Waxman is a member of the United States House of Representatives representing California's 33rd Congressional District. Representative Waxman has served in the House since 1974. He is currently Ranking Minority Member of the House Energy and Commerce Committee, the jurisdiction of which includes health care policy, regulation of prescription drugs and the pharmaceutical industry, and consumer protection, all of which are implicated by this case.

Representative Waxman has long been a leader on health issues, including health insurance reform, Medicare and Medicaid coverage, tobacco, AIDS, nursing home quality standards, women's health research and reproductive rights, and the availability and cost of prescription drugs. Most significantly for purposes of this case, Representative Waxman was one of the two principal sponsors of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly referred to as the Hatch-Waxman Amendments. That legislation, and the policies it reflects, is directly at issue in this case. Representative Waxman was also a leading advocate of the reforms to the Hatch-Waxman Amendments included in the Medicare Prescription Drug, Im-

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[1] This brief was not authored in whole or in part by counsel for a party. No one other than *amicus curiae* or his counsel made a monetary contribution to preparation or submission of this brief. A letter from counsel for the petitioner consenting to all amicus briefs is on file with the Clerk, as are letters from counsel for each of the respondents consenting to the filing of this brief.

provement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

Representative Waxman files this brief because he believes that judicial decisions shielding reverse-payment agreements between brand-name and generic drug manufacturers from stringent antitrust scrutiny stand as a significant obstacle to the fulfillment of the important public policies embodied in the Hatch-Waxman Amendments and their 2003 revisions. Those pieces of legislation sought to speed the introduction of generic competitors to brand-name drugs, not to facilitate anticompetitive agreements among pharmaceutical companies to keep generics off the market. Representative Waxman wishes to provide the Court with additional information about the policies underlying these important pieces of legislation to assist it in resolving this case.

SUMMARY OF ARGUMENT

At issue in this case is the authority of the Federal Trade Commission (FTC) to enforce the antitrust laws against anticompetitive agreements between brand-name and generic drug manufacturers that result in the withholding of generic drugs from the market. Facilitating the entry of generic drugs into the marketplace is critical to containing the cost of health care, as prices of brand-name prescription drugs continue to rise at much faster rates than other health expenses. Agreements that delay entry of generic drugs are antithetical to the policies behind both the Hatch-Waxman Amendments and their 2003 revisions, which were "designed to speed the introduction of low-cost generic drugs to market" by "facilitate[ing] the approval of generic drugs as soon as pa-

tents allow." *Caraco Pharm. Labs. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012).

In concluding that settlement agreements under which generic manufacturers are paid to keep their drugs off the market are virtually immune from antitrust scrutiny, the Eleventh Circuit and other courts that have agreed with it have turned the policy of the underlying federal legislation on its head. The Hatch-Waxman Amendments' intention was to promote competition by generic drug manufacturers. The possibility of agreements such as those involved in this case is an unintended consequence of the legislation. Hatch-Waxman was never intended to foster such agreements, still less to render the antitrust laws' prohibition of anticompetitive agreements among competitors inapplicable to agreements allowing generic manufacturers to exact a portion of a brand-name manufacturer's monopoly profits in return for withholding entry into the market.

ARGUMENT

I. Rising Prices and Expenditures for Brand-Name Drugs Burden Both Consumers and the Federal Budget.

The escalating cost of health care in the United States—and, in particular, of prescription drugs—is an enormous, nationwide problem. According to the federal Centers for Medicare and Medicaid Services (CMS), total annual health spending in this country reached $2.7 trillion in 2011, with about 10%, or $263 billion, representing retail prescription drug spend-

ing.[2] Total spending on prescription drugs, including drugs administered in hospital settings, is considerably higher but difficult to quantify because costs are not broken out. The IMS Institute for Healthcare Informatics estimated in April 2012, however, that total prescription drug spending in 2011 reached $320 billion.[3] Over the next decade, expenditures are expected to rise still further, with total health spending reaching nearly $4.8 trillion and retail prescription drug sales exceeding $483 billion.[4]

This ever-increasing spending on prescription medications burdens not only consumers but also, increasingly, the federal government. With the implementation in 2006 of the Medicare Part D prescription drug benefit, federal expenditures on prescription drugs jumped substantially. By 2010, federal spending on prescription drugs reached approximately $84 billion, with Medicare accounting for nearly $60 billion of the total, and the rest primarily attributable to Medicaid and military spending.[5] By 2021, CMS esti-

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[2] CMS, *National Health Expenditures 2011 Highlights* 1-2, www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf.

[3] IMS Inst. for Healthcare Informatics, *The Use of Medicines in the United States: Review of 2011* 19 (2012), www.imshealth.com/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/IHII_Medicines_in_U.S_Report_2011.pdf.

[4] CMS, *National Health Expenditure Projections 2011-2021*, Table 2, www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2011PDF.pdf.

[5] GAO, *Drug Pricing: Research on Savings from Generic Drug Use* 6 (2012), www.gao.gov/assets/590/588064.pdf.

mates that Medicare prescription drug spending will have more than doubled, to almost $136 billion; Medicaid prescription drug spending will exceed $52 billion; and other federal prescription drug spending will reach $18 billion, for a total of more than $200 billion.[6]

Over the past several decades, increases in health costs have substantially outstripped general inflation rates, with the result that health expenditures have markedly increased as a share of gross domestic product (GDP). Health expenditures rose from 5.2% of GDP in 1960, to 7.2% in 1970, 9.2% in 1980, 12.5% in 1990, and 13.8% in 2000, then jumped to 17.9% by 2010.[7]

Meanwhile, prescription drug spending increased significantly as a percentage of overall health spending. According to the Government Accountability Office (GAO), "Prescription drug spending as a share of national health expenditures increased from 5.8 percent in 1993 to 10.7 percent in 2003 and was the fastest growing segment of health care expenditures."[8] Since then, prescription drug spending has increased roughly in line with overall health spending, so that prescription drug expenditures continue to represent

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[6] CMS, *National Health Expenditure Projections*, *supra*, Table 11.

[7] CMS, *National Health Expenditures Tables*, Table 1, www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/tables.pdf.

[8] GAO, *PRESCRIPTION DRUGS: Price Trends for Frequently Used Brand and Generic Drugs from 2000 through 2004* 1 (2005), www.gao.gov/new.items/d05779.pdf.

about 10% of the nation's still growing expenditures on health care.[9]

Not only has overall spending on prescription drugs continued to increase even in the face of economic conditions that have suppressed demand, but prescription drug *prices* have continued to rise faster than the prices of medical services generally, and much faster than overall consumer prices. A 2011 GAO study found that from 2006 through the first quarter of 2010, prices for 100 commonly prescribed drugs rose by a total of nearly 30%, with annual increases ranging from a low of 5.4% to a high of 8.1%.[10] Meanwhile, the medical consumer price index, which measures the inflation rate for all medical services and goods, rose between 2.8% and 4.7% annually over the same period, while the overall inflation rate reflected in the urban consumer price index averaged only 2.2%.[11] An AARP study of a broader range of over 500 prescription drugs found that while drug price increases lagged a bit behind the general inflation rate in 2005, 2006, and 2007, drug prices continued to rise after the economy went into recession, so that the rate of increase in drug prices exceeded that of the overall urban consumer price index in 2008.[12]

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[9] CMS, *National Health Expenditures 2011 Highlights*, *supra*, at 2.

[10] GAO, *Prescription Drugs: Trends in Usual and Customary Prices for Commonly Used Drugs*, at 16-17 (2011), gao.gov/assets/100/97284.pdf.

[11] *Id.* at 16.

[12] Stephen W. Schondelmeyer & Leigh Purvis, *Rx Price Watch Report: Trends in Retail Prices of Prescription Drugs Widely Used by Medicare Beneficiaries 2005 to 2009*, at 2 (2012),

(*Footnote continued*)

By 2009, the rate of inflation of drug prices hit 4.8%, even as the urban consumer price index *deflated* by .3%.[13]

These prescription drug price increases, and the resulting increases in overall prescription drug expenditures, are entirely attributable to the prices of brand-name drugs. Generic prices, on average, are about 75% lower than prices for brand-name drugs.[14] Thus, although about 80% of prescriptions written annually in the United States are filled by generic drugs, generics account for only about 27% of national prescription drug spending.[15]

Moreover, brand-name and generic drug prices have headed in opposite directions over the last several years: Brand-name prices have risen sharply, while generic drug prices have *fallen*. The GAO, for example, found that the brand-name drugs in its 2011 study rose in price by a total of 37.7% from 2006 to the first quarter of 2010, with annual increases ranging from 7.1% to 9.6%.[16] Meanwhile, the generic drugs studied fell in price in every year studied, with a total drop in price over the study period of 9.9%.[17] Similarly, AARP's analysis showed that generic drugs fell in

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www.aarp.org/content/dam/aarp/research/public_policy_institute/health/rx-pricewatch-march-2012-AARP-ppi-health.pdf.

[13] *Id.*

[14] GAO, *Drug Pricing: Research on Savings from Generic Drug Use*, *supra*, at 1.

[15] IMS, *The Use of Medicines in the United States*, *supra*, at 26.

[16] GAO, *Prescription Drugs: Trends in Usual and Customary Prices*, *supra*, at 18-19.

[17] *Id.*

price every year from 2005 through 2009, dropping by 7.8% in 2009 while brand-name prices rose by 8.3%.[18]

A more recent survey by the pharmacy benefits management company Express Scripts indicates that these trends are intensifying: Over the nearly five-year period from 2008 through the third quarter of 2012, Express Scripts found that prices for a commonly prescribed market basket of brand-name drugs had increased by a whopping 63%, compared with an increase of only 9% in the overall consumer price index for the same period.[19] Prices for a market basket of commonly used generics, by contrast, had fallen 39% over the same period, with a nearly 22% drop in 2011 alone.[20]

Indeed, pricing of brand-name drugs has in recent years been so high as to produce increases in overall drug prices and spending even in the face of falling overall demand for prescription drugs attributable to economic difficulties, falling generic drug prices, and shifts in prescriptions from brand-name to generic drugs.[21] As AARP concluded, "the continued growth in drug prices for the brand and specialty market baskets has more than offset the still substantial decreases in retail prices for generics."[22]

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[18] Schondelmeyer & Purvis, *Rx Price Watch Report*, *supra*, at 3, 5.

[19] Express Scripts, *Drug Trend Quarterly* 15 (Nov. 2012), http://digital.turn-page.com/i/95262.

[20] *Id.*

[21] *See* IMS, *The Use of Medicines in the United States*, *supra*, at 19-26.

[22] Schondelmeyer & Purvis, *Rx Price Watch Report*, *supra*, at 5.

The disparities between generic and brand-name drug prices underscore the critical importance of promoting the introduction of generic drugs at the earliest date consistent with the legitimate rights of brand-name drug manufacturers under our patent laws and the Food, Drug, and Cosmetic Act. Estimates of the savings realized by the substitution of generic for brand-name drugs exceed $1 trillion for the twelve-year period from 1999 to 2010, with savings of $157 billion in 2010.[23] For Medicare Part D alone, estimated savings from the substitution of generic for brand-name drugs were $33 billion in 2007.[24]

A large portion of the amount saved through the use of generics is directly attributable to the expiration of patent protection for brand-name drugs. In 2011, one estimate of the "dividend" to the nation of savings resulting from the expiration of prescription drug patents was $14.9 billion, and the total over the five years from 2007 to 2011 was approximately $65 billion.[25]

These savings, however, are not realized when brand-name drug manufacturers extend their monopolies beyond the period in which they may legitimately claim patent protection (often by making dubious claims of patent protection for features of their products other than their basic design and use). One study concluded, for example, that delays ranging from 21 to 33 months in the availability of generic substitutes

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[23] GAO, *Drug Pricing: Research on Savings from Generic Drug Use*, *supra*, at 10.

[24] *Id.*

[25] IMS, *The Use of Medicines in the United States*, *supra*, at 19.

for three drugs—delays partly attributable to invalid claims of patent protection after earlier patents had expired—cost the Medicaid program alone more than $1.5 billion between 2000 and 2004.[26]

Pay-for-delay settlements that allow brand-name drug manufacturers to preserve their monopolies regardless of the actual validity of their patent claims thus have the potential to impose substantial costs on consumers and the federal government and to aggravate the serious national problem of excessive prescription drug prices and spending. The Congressional Budget Office (CBO) has conservatively estimated that eliminating pay-for-delay settlements postdating November 2009 (while leaving in place earlier settlements) could save $11 billion over the ten-year period from 2012-2021.[27] The CBO's estimate, however, preceded the availability of data indicating that the number of potential pay-for-delay settlements has increased markedly: The FTC has reported a record 40 such settlements in fiscal year 2012 alone.[28] The FTC

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[26] Aaron S. Kesselheim, Michael A. Fischer & Jerry Avorn, *Extensions of Intellectual Property Rights and Delayed Adoption of Generic Drugs: Effects on Medicaid Spending*, 25 Health Affairs 1637, 1643 (2006), http://content.healthaffairs.org/content/25/6/1637.full.html.

[27] CBO, *Cost Estimate: S. 27, Preserve Access to Affordable Generics Act* 5-6 (2011), http://aging.senate.gov/publications/s27.pdf.

[28] FTC, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, at 1 (2013), www.ftc.gov/os/2013/01/130117mmareport.pdf.

currently estimates that the annual cost to consumers of pay-for-delay settlements is $3.5 billion.[29]

II. The Hatch-Waxman Amendments Were Intended to Protect Consumers Against Excessive Drug Costs by Enhancing Competition Between Brand-Name and Generic Drug Manufacturers.

The Hatch-Waxman Amendments, enacted in 1984, attempted to address the problem of high prescription drug prices by encouraging competition against brand-name drugs from generic drugs. The legislation established a procedure whereby a manufacturer could obtain accelerated FDA approval of a generic drug by filing an "abbreviated new drug application," or ANDA, and demonstrating the drug's equivalence to an already-approved brand-name drug. 21 U.S.C. § 355(j). Moreover, the generic manufacturer could obtain permission to begin marketing a drug within the term of an existing patent by certifying either that the patent was invalid or that it would not be infringed by manufacture of the generic. *Id.* § 355(j)(2)(A)(vii)(IV). The legislation further encouraged introduction of generic versions of patented drugs by granting the first generic manufacturer to file a challenge to a patent on a brand-name drug a 180-day period of marketing exclusivity for the generic drug, beginning on the earlier of the first day of commercial marketing, or the date of a judicial deci-

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[29] FTC, *FTC Study: In FY 2012, Branded Drug Firms Significantly Increased the Use of Potential Pay-for-Delay Settlements to Keep Generic Competitors off the Market* (Jan. 17. 2013), www.ftc.gov/opa/2013/01/mmarpt.shtm.

sion holding the patent on the drug to be invalid or not infringed. *Id.* § 355(j)(5)(B)(iv).

Of course, the Hatch-Waxman Amendments did not abrogate the patent rights of manufacturers of brand-name drugs. Rather, they sought to speed resolution of disputes over the validity and scope of drug patents by requiring a company filing an ANDA to give notice to the patent-holder, and by providing a 45-day period within which the patent-holder could obtain a 30-month stay of the FDA's approval of the ANDA if it filed a patent infringement action against the generic manufacturer. *Id.* §§ 355(j)(2)(B) & (j)(5)(B)(iii). The Amendments further required that any such infringement action be expedited. *Id.* § 355(j)(5)(B)(iii). Absent an infringement action, the Amendments directed the FDA to approve a proper ANDA within 180 days of filing, with the approval effective immediately. *Id.* § 355(j)(5)(A).

The Amendments contained other provisions aimed at encouraging innovation in the development of prescription drugs by granting an extended term to drug patents to take into account delays in FDA approval that otherwise could cut into the value of a patent on a drug, *see* 35 U.S.C. § 156, and by granting innovative new drugs periods of market exclusivity during which no generic drugs could be approved, *see* 21 U.S.C. §§ 355(c)(3)(D) & (j)(4)(D). The Amendments thus sought to achieve a careful balance between their objectives of protecting legitimate patent rights and encouraging generic competition. *See* 130 Cong. Rec. 24425 (Sept. 6, 1984) (statement of Rep. Waxman) (describing "fundamental balance of the bill").

Notwithstanding the Amendments' concern for legitimate patent rights, the purpose of their provisions concerning generic drugs was clear: "to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962." H.R. Rep. No. 98-857, Pt. 1, at 14 (June 21, 1984). The Amendments reflected the concern that then-existing FDA procedures, which required generic drug manufacturers to complete the lengthy process for new drug approval after patents protecting the brand-name drug expired, "had serious anti-competitive effects," the result of which was "the practical extension of the monopoly position of the patent holder beyond the expiration of the patent." H.R. Rep. No. 98-857, Pt. 2, at 4 (Aug. 1, 1984). Through the ANDA procedure, which speeded approval for generics that were equivalent to approved drugs, the Amendments sought to combat these anticompetitive effects and to "implement the policy objective of getting safe and effective generic substitutes on the market as quickly as possible after the expiration of the patent" on the original drug. *Id.* at 9.

But the Amendments' framers did not limit their efforts to permitting licensing of generic drugs only after expiration of patents on brand-name drugs; rather, they made clear that "a generic manufacturer may request FDA approval to begin marketing before the patent on the drug has expired," so long as it alleges "that the existing patent is invalid or will not be infringed." *Id.* at 5. By placing the burden on the patent-holder to initiate litigation and by providing only for a limited stay of FDA approval of the generic even if such litigation were sought, the drafters provided that "the FDA will approve the generic application, even if the drug is still on patent." *Id.* Moreover, the

legislation's backers rejected amendments that would limit FDA authority to license generic versions of patented drugs because such amendments would "substantially delay generics from getting onto the market when they seek to challenge the validity of a patent." *Id.* at 10.

The ultimate goal of the Amendments was to "provide[] low-cost, generic drugs for millions of Americans," resulting in "a significant savings to people who purchase drugs." 130 Cong. Rec. 24427 (Sept. 6, 1984) (statement of Rep. Waxman). The Amendments aimed to "do more to contain the cost of elderly care than perhaps anything else this Congress has passed, because [they] will bring about lower priced generic alternatives to brand-name drugs once the patent has expired or if there is no valid patent and the courts decide that there is no valid patent in order to give that monopoly protection." *Id.* (statement of Rep. Waxman).

III. Congress Reaffirmed Its Commitment to Competition Between Generic and Brand-Name Drugs When It Passed the Medicare Drug Benefit Legislation of 2003, Which Contained New Provisions to Combat Abuses That Had Arisen After Hatch-Waxman.

Although the Hatch-Waxman Amendments achieved the purpose of streamlining the approval of generic versions of brand-name drugs, two decades of experience under the Amendments showed that pharmaceutical companies were sometimes able to use anticompetitive devices to thwart the objective of promoting competition from generic drug manufacturers. Concerns that drug manufacturers were able

to "'game' the system" ultimately led Congress to include in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, new provisions that underscored the pro-competitive purposes of the Hatch-Waxman Amendments. 149 Cong. Rec. S8190 (June 19, 2003) (statement of Sen. McCain) (quoting testimony of former FTC Chairman Timothy Muris); *see also id.* at S8193 (statement of Sen. Gregg) ("What we saw, regrettably, under Hatch-Waxman, was there were games being played.").

The concerns that led to the 2003 amendments largely involved two devices employed by brand-name manufacturers to slow generic competition against drugs claiming patent protection. The first was abuse of the 30-month stay of FDA approval once patent infringement litigation was filed: Pharmaceutical companies, Congress learned, had been able to obtain multiple, successive 30-month stays by invoking multiple patents allegedly protecting the same drug, resulting in "basically interminable stays." 149 Cong. Rec. S8193 (June 19, 2003) (statement of Sen. Gregg).

The second device that provoked Congress's disapproval (and that has led to this case) was the use of settlement agreements in patent litigation, where a manufacturer of a brand-name drug paid a generic manufacturer that had filed an ANDA to withhold the generic drug from the market even after the expiration of the 30-month stay on FDA approval. A 2002 Senate Report explained the problem as follows:

> The pharmaceutical industry has been able to reap significant profits by selling vitally .important drugs to all consumers, especially senior citizens. However, the industry has recently wit-

> nessed the creation of pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower-cost drugs off the market. Agreeing with smaller rivals to delay or limit competition is an abuse of the Hatch-Waxman law that was intended to promote generic alternatives. ....
>
> Under Hatch-Waxman, manufacturers of generic drugs are encouraged to challenge weak or invalid patents on brand name drugs so consumers can enjoy lower drug prices. The law as it stands gives temporary protection from competition to the first manufacturer that gets permission to sell a generic drug before the patent on the brand name drug expires, giving the generic firm a 180-day head start on other companies making generic versions of the drug. The Federal Trade Commission reports that some firms are exploiting that provision of law by entering into secret deals to allow a maker of the generic drug to claim the 180-day grace period in order to block other generic drugs from entering the market, while at the same time getting paid by the brand name manufacturer for withholding sales of the generic version.

S. Rep. No. 107-167, at 4 (June 20, 2002).[30]

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[30] Senate Report No. 107-167 concerned legislation passed by the Senate but not the House during the 107th Congress, which contained provisions that were ultimately included in the Hatch-Waxman Amendment revisions passed by the 108th Congress as part of the 2003 Medicare drug benefit legislation. There is no separate report concerning the amendments as enacted in the 108th Congress, other than a very brief discussion in the Confer-

(*Footnote continued*)

The Senate Report went on to explain how the economics of the prescription drug market created incentives for such anticompetitive agreements:

> Both the initial introduction of the generic version of the drug and the subsequent marketing of competing generic versions of the drug could be delayed if the [patent-holder] and the generic drug firm reach an agreement under which the generic firm delays or abstains from marketing its version of the drug. Such agreements may be attractive to both firms, because the price charged for the generic version of a drug generally is significantly lower than the price charged for the brand name version, and the price of the generic version drops further when competing versions enter the market. Therefore, the profit lost by the [patent-holder] following the entry of the generic version generally substantially exceeds the profit gained by the generic firm; both firms could be made better off by sharing some of that difference in profits instead of competing.
>
> Delaying or preventing the initial introduction of the generic version of a drug by the firm that filed the [first ANDA] and delaying the entry of generic versions marketed by other firms would both result in higher costs for prescription drugs to consumers and to the government.

Id. at 10.

The same concerns about anticompetitive agreements between brand-name and generic manufactur-

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ence Report focusing on other issues. H. Conf. Rep. 108-391, at 835-36 (Nov. 21, 2003).

ers that were set forth in the 2002 Senate Report were repeated in the 2003 floor debates surrounding the Medicare drug legislation. Senator Gregg, one of the principal sponsors of the amendments to the Hatch-Waxman Amendments, explained that the "games" that gave rise to the amendments included "games on the generic side where they might team up with a brand name and take advantage of the 180-day exclusivity clause and never bring the drug to market even though they had filed." 149 Cong. Rec. S8193 (June 19, 2003). Senator Collins elaborated on the problem of anticompetitive settlement agreements between brand-name and generic manufacturers:

> One case involved the producer of a heart medication which brought a lawsuit for patent and trademark infringement against the generic manufacturer in early 1996. Instead of asking the generic company to pay damages, however, the brand name manufacturer offered a settlement to pay the generic company more than $80 million in return for keeping the generic drug off the market. In the meantime, the consumers of this heart medication, which treats high blood pressure, chest pains, and heart disease, were paying about $73 a month, while the generic would have cost them only $32 a month.

Id. at S8194.

The 2003 reforms sought to further the Hatch-Waxman Amendments' original goals of speeding the introduction of generic drugs to the market in a number of ways. First, they altered the 30-month stay provisions to address the problem of generics being blocked by multiple, successive stays. *See* Pub. L. No. 108-173 § 1101, 117 Stat. 2448 (amending 21 U.S.C.

§ 355(j)). Second, they added provisions to enhance the ability of a generic manufacturer that had filed an ANDA to bring a declaratory judgment action with respect to the validity or infringement of a patent covering the brand-name drug even if the brand-name manufacturer did not itself bring an infringement action, thus expediting the elimination of uncertainty that might otherwise inhibit marketing of the generic version. *See id.* § 1101(a)(2)(C), 117 Stat. 2450 (adding 21 U.S.C. § 355(j)(5)(C)). Third, and most importantly here, the amendments required that all agreements between brand-name and generic manufacturers concerning the marketing of drugs subject to an ANDA be submitted to the FTC and the Justice Department for review, and provided that the generic manufacturer would forfeit its 180-day exclusivity rights if, as a result of enforcement action by either the FTC or the Justice Department, such an agreement were found to violate the antitrust laws or the FTC Act. *Id.* § 1102, 117 Stat. 2458-59, *codified at* 21 U.S.C. § 355(j)(5)(D); *id.* §§ 1111-18, 117 Stat. 2461-64, 21 U.S.C. § 355 note.

By subjecting agreements of the type at issue in this case to stringent governmental scrutiny and providing an additional penalty if they were found to violate the antitrust laws, the 2003 reforms underscored that the Hatch-Waxman Amendments were never intended to foster such anticompetitive arrangements. Indeed, the 2003 revisions were specifically designed to counter anticompetitive practices that had arisen in the years following the Amendments' passage and to re-emphasize the Hatch-Waxman Amendments' original goal of enhancing competition between generic and brand-name drug manufacturers.

IV. Shielding Pay-for-Delay Settlements from Antitrust Liability Undermines the Hatch-Waxman Amendments' Pro-Competitive Policy.

This Court has recently had occasion to emphasize that the Hatch-Waxman Amendments should be construed to give effect to their overarching goal of increasing competition in the pharmaceutical marketplace by accelerating the introduction of generic drugs. *See Caraco*, 132 S. Ct. at 1676, 1681-88. But in the decision below and in its previous decision in *Schering-Plough Co. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), the Eleventh Circuit turned the pro-competitive policy embodied in the Hatch-Waxman Amendments and their 2003 revision on its head by asserting that the provisions of the Amendments somehow provided a *justification* for agreements under which generic manufacturers withhold their products from the market in return for payments from brand-name drug makers.

In *Schering-Plough*, quoting *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003), the Eleventh Circuit criticized the FTC for "neglect[ing] to understand" that "reverse payments are a natural by-product of the Hatch Waxman Act process." 402 F.3d at 1074. Similarly, a divided panel of the Second Circuit asserted that "reverse payments are particularly to be expected in the drug-patent context because the Hatch-Waxman Act created an environment that encourages them." *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 206 (2d Cir. 2006). These courts appear to have concluded that because the Amendments created a situation where generic drug manufacturers *could*

extract settlement payments in return for keeping their products off the market, such agreements were competitively justified and, indeed, endorsed by the Hatch-Waxman Amendments.

To be sure, the Amendments enhanced the bargaining position of generic manufacturers in settlement negotiations by removing regulatory barriers to their entry into the market. But the reason the Amendments enhanced the position of the generics was to encourage them to enter the market, *not* to authorize them to use their increased leverage to exact a share of a brand-name drug owners' monopoly profits in return for *staying out of the market*. Courts that have rejected antitrust scrutiny of reverse payment settlements have confused an unintended consequence of the original legislation—its creation of incentives for anticompetitive as well as competitive behavior—with a natural and intended effect.

Other courts and judges, by contrast, have correctly recognized that the opportunities for anticompetitive agreements were by no means *natural* outgrowths of the Hatch-Waxman Amendments' purposes, but distortions of its intended effect. As the Third Circuit has put it, "The goal of the Hatch-Waxman Act is to increase the availability of low cost generic drugs. ... That goal is undermined by [allowing] the patent holder to pay its potential generic competitors not to compete." *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 217 (2012). Likewise, in *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98 (2d Cir. 2010), a panel of the Second Circuit, although holding itself bound by the earlier *Tamoxifen* decision to uphold the legality of a reverse-payment settlement, called on the Second Circuit to reconsider its

approval of such settlements in light of their inconsistency with the policies of the Hatch-Waxman Amendments. *Id.* at 108-10. Judge Pooler, dissenting from the court's eventual denial of rehearing, accurately observed that "exclusion payment settlements seem plainly inconsistent with the stated purpose of the Hatch Waxman Act, which is to encourage patent challenges as a way of increasing consumer access to low-cost drugs." 625 F.3d 779, 781 (2d Cir. 2010).

Even the *Ciprofloxacin* decision relied on by the Eleventh Circuit in *Schering-Plough* recognized that use of the Hatch-Waxman process to delay a would-be generic competitor's entry into the market through reverse payments is an "*unintended* consequence of altering the litigation risks of patent lawsuits." *Ciprofloxacin*, 261 F. Supp. 2d at 252 (emphasis added). Similarly, the D.C. Circuit has recognized that the statutory scheme creates an "unfortunate" opportunity for the "first applicant [to] collude[] with the pioneer drug company to eliminate generic competition." *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1067, 1072 (D.C. Cir. 1998). That result, however, is "at odds with Congress's apparent purposes, in enacting [the Hatch-Waxman Amendments], of rewarding innovation and bringing generic drugs to market quickly. Indeed, the first applicant could even collude with the original patent-holder to prolong their litigation, and thereby keep the second applicant's drug off the market indefinitely." *Id.* at 1072; *see also Biovail Corp. Int'l v. Hoechst Aktiengesellschaft*, 49 F. Supp. 2d 750, 768 (D.N.J. 1999) (stating that "taking advantage of the exclusivity period in an anticompetitive manner" would "fal[l] squarely within what the court in *Mova* speculated would be an abuse of the statute"); *In re Cardizem CD Antitrust Litig.*, 218 F.R.D.

508, 534 (E.D. Mich. 2003) (recognizing that Congress has "worked to amend Hatch-Waxman's exclusivity provisions to curb the very abuses alleged in this action"), *aff'd in part and app. dism'd in part*, 391 F.3d 812 (6th Cir. 2004).

In some sense, it may be "natural" for industry participants to respond to a statute designed to foster competition by agreeing *not* to compete in order to share higher monopoly profits—"natural" in that industry often tends toward anticompetitive behavior. But that tendency, whether "natural" or not, does not provide a competitive justification for such agreements when they are challenged under the antitrust laws—which, after all, are designed principally to curb such tendencies—nor does it demonstrate that the anticompetitive behavior is consistent with the aims of the underlying statute. Rather, "actions taken to 'subvert' [a regulatory] scheme 'for anticompetitive purposes' are subject to the antitrust laws." *Woods Exploration & Producing Co. v. Aluminum Co. of Am.*, 438 F.2d 1286, 1303 (5th Cir. 1971).

Thus, a correct approach to antitrust analysis of reverse-payment settlements should recognize that use of the Hatch-Waxman process to prevent generic competition is impermissible because it would "turn the intent of the Hatch-Waxman Act on its head" and "allow, in effect, a monopoly ... when such rights could not be obtained through the normal patent process." *Alcon Labs., Inc. v. Allergan, Inc.*, 256 F. Supp. 2d 1080, 1089 (C.D. Cal. 2003) (criticizing brand-name manufacturer's attempt to "effectively circumvent the rationale and intent of the Hatch-Waxman Act" by bringing an action for inducing infringement against a competing generic manufacturer prior to

FDA approval); *see also TorPharm, Inc. v. Thompson*, 260 F. Supp. 2d 69, 83 n.15 (D.D.C. 2003) (noting need to ensure that "the incentive structure created by the Hatch-Waxman Amendments" not "be turned on its head"), *aff'd sub nom. Purepac Pharm. Co. v. Thompson*, 354 F.3d 877 (D.C. Cir. 2004). Drug manufacturers should not be permitted to invoke the Amendments as a "sword" to promote anticompetitive conduct because "[t]hat would certainly not advance the purpose of making available 'more low cost generic drugs,' and was not what Congress intended." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1359 (Fed. Cir. 2003).

Moreover, allowing reverse-payment settlements to escape stringent antitrust scrutiny significantly undermines the effectiveness of the 2003 revisions of the Hatch-Waxman Amendments. Those revisions were designed to enhance the federal government's authority to police anticompetitive agreements between generic and brand-name drug manufacturers and to create a significant disincentive to such agreements: forfeiture of the 180-day exclusivity period granted to the first generic manufacturer to challenge a patent if the generic is found to have entered an agreement with a brand-name manufacturer that violates the antitrust laws. In enacting the provisions for FTC and DOJ review of agreements between generic and brand-name manufacturers, as well as the new forfeiture provision, Congress relied on the adequacy of *existing* principles of antitrust law to condemn agreements whereby generics withheld drugs from the market in exchange for a share of the brand-name manufacturer's monopoly profits. *See* S. Rep. No. 107-167, at 1.

The Eleventh Circuit's permissive approach to the agreement in this case, and its erroneous notion that settlement agreements involving payments to generics to keep their products off the market are a natural consequence of Hatch-Waxman, threatens to render the mechanism Congress created to police anticompetitive agreements toothless. Because it rests in part on the notion that Hatch-Waxman somehow dictates application of weaker-than-normal antitrust constraints to anticompetitive agreements such as those at issue here, the decision below stands as a significant obstacle to the accomplishment of Congress's intent, in the 2003 legislation, to correct the abuses that had arisen under the Hatch-Waxman Amendments and to shore up the Amendments' principal purpose of increasing competition in the prescription drug market for the benefit of consumers.

The Eleventh Circuit concluded its opinion in *Schering-Plough* by stating that the result it reached "reflects policy." 402 F.3d at 1076. But the policy the Eleventh Circuit followed in *Schering-Plough* and adhered to in this case was one of its own invention, not the one chosen by Congress when it enacted the Hatch-Waxman Amendments and their 2003 revisions. *Congress's* clearly stated goal was to lower drug prices by enhancing generic drug competition. The policy chosen by the Eleventh Circuit, however much it may benefit brand-name manufacturers who wish to preserve their monopoly profits and generic manufacturers who seek a slice of those profits, "is bad policy from the perspective of the consumer, precisely the constituency *Congress* was seeking to protect." *K-Dur*, 686 F.3d at 217 (emphasis added). Judicial policy preferences "should not displace countervailing public policy objectives or, in this case, Congress's determi-

nation—which is evident from the structure of the Hatch–Waxman Act and the statements in the legislative record—that litigated patent challenges are necessary to protect consumers from unjustified monopolies by name brand drug manufacturers." *Id.* The predictable result of the policy that the Eleventh Circuit has substituted for that of Congress will be less competition and higher drug prices for all Americans.

CONCLUSION

For the foregoing reasons, the judgment of the Eleventh Circuit should be reversed.

Respectfully submitted,

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